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Public governance and artificial intelligence in healthcare: a study on privacy and fundamental rights[1]

Governança pública e inteligência artificial na saúde: um estudo sobre privacidade e direitos fundamentais

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Abstract:

The article discusses the problem of the use of new technologies in healthcare. The right to privacy and intimacy of users must be observed in order to preserve the constitutionality of the application of available Artificial Intelligence instruments, as a tool to optimize access to health, with the minimum sacrifice of other fundamental rights, based on the idea of weighting. In view of the changes in healthcare archetypes, the peak of which occurred during the Covid-19 pandemic, various electronic devices have been put into operation as facilitators for monitoring activities related to dealing with illnesses and promoting well-being. However, the application of these innovative technological models must be viewed with caution, under penalty of infringing fundamental rights. Through exploratory and bibliographical research, the article analyzes technologies aimed at developing public policies to improve the medical field, with the aim of producing more effective and safer solutions, preserving health as a fundamental corollary to human rights. The difficulty of weighing up the protection of sensitive data from users of AI programs aimed at medical monitoring is addressed, due to the lack of specific regulations. In the end, there is a concrete possibility of mitigating the risks inherent in the implementation of AI-based health systems, to ensure that the benefits of their use are maintained, while safeguarding fundamental rights and constitutional guarantees, serving as a normative parameter for the construction of effective regulatory frameworks that are compatible with the preservation of user privacy and technological innovations in health.

Keywords: Artificial Intelligence; Health; Right to Privacy.

Resumo:

O artigo discute a problemática do uso das novas tecnologias no âmbito da saúde. Há a necessidade de serem observados o direito à privacidade e intimidade dos usuários, para preservar a constitucionalidade na aplicação dos instrumentos disponíveis de Inteligência Artificial, como ferramenta de otimização ao acesso à saúde, com o mínimo sacrifício dos demais direitos fundamentais, a partir da ideia de ponderação. Diante das mudanças de arquétipos de assistência médica, cujo ápice ocorreu no período da pandemia de Covid-19, diversos equipamentos eletrônicos foram operacionalizados como facilitadores de acompanhamento de atividades relacionadas ao enfrentamento de doenças e promoção de bem-estar. Todavia, a aplicação destes

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modelos tecnológicos inovadores deve ser vista com cautela, sob pena de ferir direitos fundamentais. Mediante pesquisa do tipo exploratória e bibliográfica, analisa-se tecnologias voltadas ao desenvolvimento de políticas públicas para o incremento da área médica, visando produzir soluções mais efetivas e seguras, preservando a saúde como corolário fundamental aos direitos humanos. Enfrenta-se a dificuldade de ponderar a proteção de dados sensíveis dos usuários de programas de IA, voltados para o acompanhamento médico, pela inexistência de regulamentação própria. Ao final, constata-se a existência de uma possibilidade concreta de mitigar os riscos inerentes à implementação de sistemas de saúde baseados em IA, para assegurar a manutenção dos benefícios de sua utilização, ao mesmo tempo em que se resguardam direitos fundamentais e garantias constitucionais, servindo como parâmetro normativo para construção de marcos regulatórios eficazes e compatíveis com a preservação da privacidade do usuário e as inovações tecnológicas na saúde.

Palavras-chave: *Inteligência Artificial; Saúde; Direito à Privacidade.*

1 Introduction

It has long been emphasized that the protection of health—which qualifies as an inalienable subjective right, guaranteed to all by the Constitution (art. 5, caput, and art. 196) will always prevail as a norm that eclipses this fundamental prerogative. Thus, any dilemma that places constitutional norms involving respect for health in collision with the right to privacy/intimacy must be weighed in such a manner as to ensure an interpretation that gives precedence to the inalienable right to health, since it is an individual prerogative, guaranteed to the generality of persons by the very text of the Federal Constitution.

In fact, this article deals with the application of Artificial Intelligence (AI) in the health arena as a means of implementing a significant advance that cannot be undervalued by public governance, with the objective that the Public Power—which is charged not only with legislating on the matter but also with implementing social and economic policies—does so in a comprehensive and immediate way, disseminating broad guarantees to citizens.

Accordingly, postponing or attempting to obstruct the incorporation of scientific and technological innovations associated with AI in the field of health constitutes conduct that may compromise the exploitation of potential benefits of these technologies in the improvement of health services and in the effectiveness of sectoral public policies, for the pretext that privacy and intimacy would be compromised does not hold. This is because mechanisms for the protection of data—especially sensitive data—are already available within the very technological tools at the State's disposal.

Therefore, the work in focus will address, in the first section, the right to health linked to the potentialities brought by AI, so as to verify positive impacts in terms of expanding services and, with that, adopting an assertive model for constructing new perspectives of public governance oriented toward social well-being.

In the second section, it will examine whether the provision of personal data and information necessary to meet the collective right to health violates sensitive data, and in which ways these data can be protected as a means of reconciling effective and safe care without violating the right to data protection.

It is indisputable that reaching a point of equilibrium between health and the protection of personal data is no easy task, so the solution that seems most appropriate imposes a balancing of interests, which will be addressed within this second topic.

In the third section, the study turns to the analysis of the ethical, social, and legal implications arising from the application of AI in the health field, from the perspective of fundamental rights. This topic addresses the challenges related to protecting patient autonomy, the need for informed consent, and transparency in algorithmic functioning, especially given the opacity of machine-learning–based systems. It also discusses risks associated with algorithmic discrimination, violation of sensitive data, and impacts on the humanization of medical care, as well as difficulties in attributing civil liability in cases of errors arising from AI use. Finally, it highlights the urgency of constructing a specific and robust regulatory framework capable of ensuring that technological advances are implemented in an ethical, safe, transparent manner, and compatible with constitutional principles, in order to safeguard human dignity and avoid deepening social inequalities.

It is important to note that certain rights—such as the right to health—occupy a special position, being regarded as fundamental, which means their protection is revisited with greater importance in specific cases, such as the one revealed by the hypothesis of providing certain personal information that falls within the sphere of privacy/intimacy but warrants careful balancing.

Thus, the relativization of classic legal concepts—such as the principles of privacy and intimacy—is brought into the debate so that the right to health can achieve its maximum effectiveness with the aim of promoting the broadest reach of fundamental rights. In other words, the application of new AI-driven technologies in the health domain must be used in accordance with legal requirements to harmonize those interests with the privacy of users of public services.

It is indubitable, therefore, to reach the conclusion that it falls upon the Public Power to act positively and promote the realization of the right to health with due balancing of other rights that might walk in the opposite direction. All this based on the necessary evolution of

public policy and governance concerning the fulfillment of the aforementioned fundamental rights.

To that end, the deductive method was adopted, starting from theoretical and legal analysis and deepening premises related to the use of AI in the health field and its interface with the protection of fundamental rights, especially the right to privacy, through research on indirect, documentary, and bibliographical documentation. The theoretical framework was constructed based on research through the Capes scientific journal portal, via CAFE accessing the Web of Science database, in addition to consultation of specialized journals on the Revista dos Tribunais portal, the Redalyc platform, and qualitative bibliographical research. The search was performed using the following categories: Artificial Intelligence; Right to Health; Privacy; Balancing of Principles.

The research has an exploratory and explanatory nature, since it aims to map and understand the current normative, ethical, and social panorama surrounding AI use in health and, beyond that, explain the implications and challenges arising from such application, especially regarding the protection of sensitive data and the realization of fundamental rights in public governance.

This study seeks to analyze the right to health in its current context vis-à-vis technological advances resulting from AI application, including the State's obligation to adapt in order to reconcile constitutional principles with personal data protection under the existing normative framework, and to seek harmonization with the protection of personal data, as well as evaluate the need for specific regulation.

The specific objectives of this article are: a) To inventory how AI has innovated in the field of the right to health, whose legal basis has a constitutional foundation as a social fundamental right, reinforcing its status as a right of immediate content and necessary compliance, and not merely as a guideline; b) To analyze the epistemological basis of the horizontal effectiveness of fundamental rights in relations with the Public Power, especially in the balancing of interests between the right to health and privacy/intimacy, given that data and personal information provided by the user when accessing the various technological systems at their disposal must be preserved; c) To evaluate the parameters for the application of fundamental rights in relations with the Public Power and the fulfillment of the Public Governance's duty to expand its public health policies in order to guarantee a fairer and more supportive society without pitting fundamental rights to privacy/intimacy and health against each other.

The analysis of this work is based on surveying and understanding the main arguments and counterarguments used to support the consolidation of the parameter for promoting the expansion of the right to health in an integral manner in the twenty-first century, aiming to reach an increasingly fruitful field for the user. For this purpose, the Public Power cannot shirk its readjustment so as to guarantee access to health without prejudice to data protection.

The relevance of the research consists of identifying AI's contribution in the health domain and its corresponding repercussions when observed from the perspective of Public Governance and the necessary protection of fundamental rights to privacy and intimacy.

Therefore, this is a reaffirmation of the right to health to be revisited through AI use, which profoundly interferes in public policies in this segment, since the promotion of preventive and health-promoting services inevitably handles sensitive data.

Thus, the Public Power acquires a differentiated outlook concerning reconciling the realization of health and data protection, being unable to harden policies in either of these fields.

The topic under discussion assumes as a premise that AI can contribute to carrying out governance in the public health sector more effectively, which does not limit itself to providing the traditional service of prevention and treatment of health, but must lay the foundations for care consistent with medical expectations that are evolving and improving. All of this must respect the administrative, technical, and management provisions expected to keep both citizens' health and privacy protected by constitutional commands.

In this vein, the final considerations highlight the utmost importance of applying AI in the health sphere so that State action becomes more effective for citizens. It falls upon the Public Power to generate, for people's benefit, increasingly improved technologies to conduct public governance along paths of responsibility in handling health-related data, which must be done through public policies that accompany advances brought by AI use.

2 The Use of Artificial Intelligence and Its Advancement in the Field of Health

Health was constitutionally enshrined in article 6 of the Federal Constitution as a social right. It is qualified as a subjective, inalienable right guaranteed to everyone in a universal manner regarding promotion, protection, and recovery (art. 196 of the FC). It is a

second-generation fundamental right associated with a social solidarity imperative, whose dynamic consists of performative obligations from which the Public Power cannot disengage.

According to Canotilho (1993), Sarlet and Figueiredo (2008), the existence of this social right has two effects: a positive one, according to which everyone (not limited to Brazilians) possesses the subjective right to the provision of health services by the State as constitutionally established, and a negative one (in a defensive sense), by which the State power cannot obstruct the achievement of the right to health and must, when necessary, carry out constitutionality control of norms and decisions that affront the Constitution's material objectives.

The urgency of realizing this right is so strong and binding that no State interest can minimize its effectiveness. On the contrary, public policies must promote development both in improving treatment and in preventive care, aiming to free the citizen from disease before it develops, whether through sanitary policies or through early and well-executed diagnosis, as in curative treatment through more advanced surgical techniques and medications with faster and more effective disease-fighting properties.

Within this context, it is imperative to highlight the importance of constitutional hermeneutics, which assumes special relevance regarding health realization, as it is directly linked to the right to life and human dignity itself. Therefore, public policies developed in the health area must focus, reiterating, on all perspectives: preventive, therapeutic, and curative, in order to promote integral coverage, as extracted from the concept brought by the World Health Organization (WHO), namely: "health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."[2]

It is easy to see that the right to health is guaranteed to citizens through the State's obligation to adopt necessary measures to prevent and treat epidemic diseases, and all public entities must adhere to the WHO directives, not only because they are binding under Article 22 of the World Health Organization Constitution (Decree 26,042 of December 17, 1948), but above all because they are part of the constitutional text, whose pursuit of effectiveness is necessary to give full efficacy to the right to health.

It should be emphasized that Positivism—a philosophical current that emerged in France in the early nineteenth century—exerted significant influence on the consolidation of the scientific method as a foundation for organizing knowledge and social structures. Spread

[2] Since 1948, when the WHO Constitution came into force, the World Health Organization has used the aforementioned concept of health. Translated by the authors. Source: "Frequently Asked Questions." World Health Organization. Available at: https://www.who.int/about/who-we-are/frequently-asked-questions. Accessed on: June 3, 2022.

by Auguste Comte, its main exponent, Positivism defends the centrality of empirical science and technical rationality as instruments of progress. Such a legacy remains current, especially in light of the expressive advance of AI-based technologies, which fit within the same paradigm of seeking more effective solutions grounded in evidence and oriented by objective, verifiable criteria.

Thus, it is impossible to ignore the advance that technologies have brought to society and the new production models, especially in the health area. Through various research, studies, and methods, science continuously adds value to health and improves people's quality of life, providing ever more powerful and unimaginable solutions that can contribute to making diagnostics and data clearer and more suitable for problem-solving, not only for the medical community but also for Public Governance, which will identify statistics in these elements to be used for computing volumes and indicating guidelines for conducting public policies, capable of proposing actions to meet the real needs of citizens.

To this end, the application of technological measures available on the market is indispensable within the mentioned context, which is why it is undeniable that AI assumes special relevance, since the performance of technological knowledge applied to science and medicine brings profound and essential changes that undoubtedly contribute to evolution in all fields of health activity.

At this point, for understanding the subject under examination, we must define the term "Artificial Intelligence," which refers to a machine's ability to perform activities in a way that is considered intelligent, associated with human input. It is a technological device capable of simulating human skills such as analysis, reasoning, and perception in the most diverse areas. Lobo (2017) describes AI as the simulation of human abilities that enable reasoning when faced with everyday situations requiring decision-making, with the goal of artificially reproducing the human neural network.

Currently, AI's application is noticeable in computer programs that use a broad system where the user can access games, interact with a voice-activated virtual assistant to perform tasks, control security applications, among others—gaining particular prominence in health by providing virtual medical diagnoses, decision-making tools to avoid medical errors, electronic medical records, robotic surgeries, patient data analysis, more complete diagnoses in less time, and through more modern machines with more precise image and data analyses, among others.

To fulfill the constitutional desideratum regarding the full realization of the right to health, as well as the WHO directives, new technologies are important allies of public governance, since using various devices and techniques linked to AI in health serves to favor the creation and expansion of public policies aligned with the integrality of the concept previously referred to by the WHO.

From this perspective, the aforementioned organization, through a report on the challenges and risks of AI use in health, listed six principles aimed at ensuring AI's proper functioning so that it plays a functional role in all countries, limiting risks and expanding the possibilities of technology as a basis for regulation by public governance, namely:

> 1.Protect Human Autonomy: In the health care context, this means that humans must retain control over health systems and medical decisions; privacy and confidentiality must be protected; and patients must give valid informed consent through appropriate legal frameworks for data protection.
> 2. Promote Human Well-Being, Safety, and Public Interest: AI technology designers must meet regulatory requirements for safety, accuracy, and efficacy for well-defined use cases or indications. Quality control measures must be available in practice, as well as quality improvement in AI use.
> 3. Ensure Transparency, Explainability, and Understandability: Transparency requires that sufficient information be published or documented before designing or deploying an AI technology. This information should be easily accessible and facilitate meaningful public consultation and debate about how the technology is designed and how it should or should not be used.
> 4. Foster Accountability and Responsibility: Although AI technologies perform specific tasks, it is stakeholders' responsibility to ensure they are used under appropriate conditions and by properly trained personnel. Effective mechanisms must be available for redress for individuals and groups adversely affected by algorithm-based decisions.
> 5. Ensure Inclusion and Equity: Inclusion requires that health AI be designed to encourage the broadest possible equitable use and access regardless of age, sex, gender, income, race, ethnicity, sexual orientation, ability, or other characteristics protected by human rights codes.
> 6. Promote AI That Is Responsive and Sustainable: Designers, developers, and users must continuously and transparently evaluate AI applications during actual use to determine if they respond adequately to expectations and requirements. Systems must also be designed to minimize environmental consequences and increase energy efficiency. Governments and companies must address anticipated workplace disruptions, including training health professionals to adapt to AI systems and potential job losses due to automation.
> (WHO, 2021, pp. 12–14)

Another important point that deserves emphasis for understanding the work in focus is the great scientific advance brought by the twenty-first century, which assumed special prominence due to advancements in the health arena, especially during the Covid-19 pandemic.

During that period, there was an impressive boost in the practice of medicine, science, and technology, which moved in real harmony with AI in the effort to save lives. Accordingly, some demands gained greater relevance, such as vaccine development; remote care

techniques; remote patient monitoring; faster and more accurate clinical results; electronic prescriptions and orders; near real-time disease data collection; among other examples.

There are also systems that use patient data to help identify symptoms and diseases that can be difficult for doctors to detect; help develop potential drugs more quickly and with greater accuracy; monitor vital signs in real time; administer precise medication dosages for treating diseases, significantly reducing medical errors; promote digital mapping of areas of the human body; perform less invasive surgeries; monitor disease progression and medication distribution for treatment; check sanitary and epidemiological data—these are also examples of the topic's prominence.

It should be noted that the efforts employed at the time aimed to achieve greater effectiveness in health within the shortest possible time to save lives while the world desperately sought a solution, given there was no standard to control disease spread or a cure for the virus.

Thus, AI is used in medical diagnoses and treatments such as guided punctures, robotic surgeries, bed control, more accurate imaging and reports provided by machines themselves, among many other examples. Therefore, it is imperative to conclude that the Covid-19 pandemic was a driving force behind AI's great expansion in health.

Consequently, AI tools serve, in the current context, to identify significant relationships in raw data with the potential to be applied in various areas of medicine, whether in the final medical field or in operational and financial decision-making in health management, such as hospital management, discharge control, bed occupancy, patient reallocation in various medical-hospital treatment centers, thereby making resource application more balanced.

In other words, there are numerous mechanisms for using technologies that AI can employ in health, generating positive results capable of producing decisions and presenting solutions to managers when conducting public health policies—solutions that are likely to evolve.

In this sense, it is necessary to acknowledge that AI is a powerful ally of public governance, since much of the data obtained enables the enhancement of programs that are already available, as well as others that may be developed in the future according to citizens' needs—all so that the State can fulfill its mission.

From the premise that public policies are created by objective factors to promote rights and guarantees aligned with the constitutional text, it is inexorable to conclude that data

obtained from new technologies go hand in hand to create, enhance, and improve projects in benefit of health.

Technological evolution brought by AI aims to bring solutions to situations that deserve due attention from the State to serve all citizens, especially when the matter concerns a theme as sensitive and fundamental as health and quality of life, both of which are inextricably linked to the realization of fundamental rights and, ultimately, citizenship itself.

In this vein, AI utilization uses algorithmic mapping capable of showing health indicators, as well as numbers to draw statistics for health policies, defining behavioral modulation patterns (such as: cellphone use, apps, virtual consultations, among others), which facilitates data capture for implementing more well-developed health projects by the State, which will know where and how to apply public resources, since concrete data on needs are at the Public Power's disposal to use a given technology for society's benefit.

In truth, public governance has efficiency among its pillars and, as such, it is impossible to ignore improving public policies with the goal of achieving better health management, so that investments in new technologies become part of the budget and contribute to a balanced management of population access to more instrumented State protection through democratization mechanisms of information and communication technologies (ICTs), emphasizing the State's role in guaranteeing rights to health, life, and equal treatment for the population.

Effective results are thereby achieved: better quality of care, optimized time and cost, since the concentration of machines and devices in a specialized medical unit enhances faster, safer, and less error-prone diagnosis, given time is a decisive factor in formulating diagnoses and combating diseases.

The realization of an urgent right such as health demands respect from the public administrator for a legal ethic associated with the imperatives of social solidarity and, ultimately, human dignity. Therefore, the care expected from Public Governance is always positive and responsible, obeying Federal Constitution commands—especially to observe fundamental rights, according to principles listed by the WHO and already cited above.

Thus, AI has emerged and been refined in recent years as a value-adding agent for use by the State. Public Governance can leverage AI to its advantage, since it has the capability to process data via algorithms that tend to improve through self-learning and to propose increasingly precise diagnostic hypotheses. In this sense, one observes that using such systems can perfectly simulate the human mind, with synapses and logic, but in mere

milliseconds and with extraordinary, extensive performance (Cardin; Cezelatto; Oliveira, 2022).

Obviously, all this requires continuous concern with the quality of medical training and the perception that the health professional is not dispensable. On the contrary, it is firmly understood that the human contact between doctor and patient remains the most important therapeutic agent—not only for guidance but also for interpreting results and for fundamental human contact to address patients' needs, doubts, and concerns, which no machine can replace. Taking into account this singularity of humans, in Arendt's (2009) expression, which allows them to be both equal and different, in the paradoxical plurality of singular beings, the machine cannot replace the human.

It is imperative to highlight that AI use in the health field causes concern for many, including international organizations, with special emphasis on the World Health Organization, which, imbued with the intention of guiding institutions and governments, elaborated a document on Ethics and Governance of AI for Health (WHO, 2021)—the result of "eighteen months of deliberation conducted among leading experts in ethics, digital technology, law, human rights, as well as technical officials from Ministries of Health" (Rodrigues, 2022, p. 134).

The cited WHO Guidance advances AI adoption regarding drug production, stating that "in the next two decades, with the aid of AI it will be possible to facilitate the discovery and development of new drugs, and possibly soon, drug testing will be virtual." In other words, in the near future, animal and human participation in tests could be dispensed with "and, thus, see the emergence of precision medicine or healthcare individually tailored to a person's genes, lifestyle, and environment" (Rodrigues, 2022, p. 134).

> At present, drug development is led either by humans or by AI with human oversight. In the next two decades, as work with machines is optimized, the role of AI could evolve. Computing is starting to facilitate drug development by finding novel leads and evaluating whether they meet the criteria for new drugs, structuring unorganized data from medical imaging, searching large volumes of data, including healthcare records, genetics data, laboratory tests, the Internet of Things, published literature and other types of health big data to identify structures and features, with recreating the body and its organs on chips (tissue chips) of AI analysis (39,42). By 2040, testing of medicine might be virtual—without animals or humans—based on computer models of the human body, tumours, safety, efficacy, epigenetics and other parameters. Prescription drugs could be designed for each person. Such efforts could contribute to precision medicine or healthcare individually tailored to a person's genes, lifestyle, and environment. (WHO, 2021[3])

[3] Currently, drug development is led either by humans or by AI with human oversight. Over the next two decades, as work with machines becomes optimized, the role of AI may evolve. Computing is beginning to

The advent of the internet re-signified data, which became valuable assets, inevitably making privacy a special object of attention. In this sense, it is important to highlight Rodotà's lessons (2013, pp. 74–75), who affirms that guaranteeing privacy, considered in isolation, does not constitute any precise rule that prevents the circulation of information—including personal data—once one cannot ignore the social and institutional contexts in which such data are historically inserted for limiting access.

Therefore, it is impossible not to underscore that AI has brought incalculable benefits to health, as it makes many practices successful and facilitates the understanding of results, which not only improve disease detection but also enable early treatment, facilitate exam analysis, make more targeted public policies possible, and allow public administrators to adopt more efficient regulatory measures, as previously stated.

Nonetheless, all this implies the provision of personal data, often sensitive, whose harmonization with the right to privacy and intimacy demands reflection based on a balancing of constitutional principles, which will be addressed in the next topic.

3 Challenges of Applying Artificial Intelligence Due to Handling Sensitive Data and the Right to Privacy

Just like most areas of social policy, public health has traditionally been considered a sensitive domain where the State frequently is the dominant instance for organizing and providing related policies (Riggirozzi, 2020). The so-called Internet of Medical Things is the expression used to point to the use of smart objects in the health field aiming to promote faster diagnosis and the possibility of remotely monitoring patients (Sarlet, 2020).

AI use in health is not exhausted in diagnosis, given the provision of data to monitor patient evolution in medical care—for example, treatment administration by the patient themselves, as well as through apps for medication management, among other aspects, all intended to assist the treatment protocol in the best possible way (Rodrigues, 2022).

facilitate drug development by finding novel leads and evaluating whether they meet the criteria for new drugs, structuring unorganized data from medical imaging, searching large volumes of data—including health records, genetic data, laboratory tests, the Internet of Things, published literature, and other types of health big data—to identify structures and features, with the recreation of the body and its organs on chips (tissue chips) for AI analysis (39, 42). By 2040, drug testing may be virtual—without animals or humans—based on computer models of the human body, tumors, safety, efficacy, epigenetics, and other parameters. Prescribed medications could be designed for each individual. Such efforts could contribute to precision medicine or healthcare individually tailored to a person's genes, lifestyle, and environment (WHO, 2021).

It is vital to underscore the unquestionable relevance of telemedicine use, especially during the Covid-19 pandemic, making remote contact possible through various communication channels.

In this regard, recognizing the importance of this new reality, the Federal Council of Medicine enacted Resolution No. 2.314/2022, highlighting innovation and the development of new digital information and communication technologies that facilitate information exchange between doctors and between doctors and patients. Conversely, it emphasized the need to ensure the ethical and legal precepts involved (Federal Council of Medicine, 2022).

The aforementioned Resolution stipulated that a physician using telemedicine, aware of their legal responsibility, must evaluate whether the information received is qualified—within strict digital security protocols—and sufficient for the proposed purpose. Regarding the patient, their information can only be transferred to another professional with prior permission through free and informed consent and with security protocols capable of ensuring confidentiality and data integrity (Federal Council of Medicine, 2022).

It should be noted that during any telemedicine treatment, explicit consent must be guaranteed, in which the patient or their legal representative must be aware that their personal information may be shared and of their right to deny permission for such sharing, except in medical emergencies (Federal Council of Medicine, 2022).

In 2020, doctors, nurses, and other health professionals drafted a document with the aim of providing recommendations and guiding care delivery by staff to enable better communication in the pandemic context. Thus, a virtual visit protocol was established to maintain psychological support for the patient throughout hospitalization, given the absence of in-person visits, using available technologies and AI to do so (Crispim, 2020).

Given the widespread use of AI and information sharing, especially in health a pressing need arose to expand and consolidate regulatory norms to guarantee ethics and privacy in processing personal and sensitive data. On this subject, Dourado and Aith (2022, p. 6) contribute significantly to the debate:

> The application of the right to explanation in health must address specific complexities of regulating AI for clinical use. Starting from the understanding that this right is now present in Brazilian legislation, it will be up to regulatory bodies to delineate its scope and mechanisms for implementing it. In addition to the National Data Protection Authority's actions, there must be intervention by other regulatory bodies, such as the National Health Surveillance Agency and authorities regulating regulated professions, like medical councils.

Clearly, there is no doubt that appropriate data use in public health can generate public interest; however, to guarantee the public good, rules and regulations must be crystal clear. Public health data have some public good characteristics, as they can improve health collectively, but, on the other hand, individual health data are sensitive personal information. Therefore, data processors must provide convincing evidence that their research can create a greater public good than the existing risk (IDEC, 2022).

It is worth emphasizing that family history, immune system status, use of medications, alcohol, and drugs—along with the social environment and behavioral patterns—are examples of types of personal data that can feed into AI, providing advances in health care. However, in a context without regulation, without transparency and ethics, privacy violations are possible, and the use of personal health data could exacerbate discrimination, inequality, and make access more costly (IDEC, 2022).

The Federal Constitution, in its art. 5, X, determines that intimacy, private life, honor, and image of persons are inviolable, ensuring the right to compensation for material or moral damage resulting from their violation (Brazil, 1988). Evidently, the activity of collecting, processing, and storing data, especially in the health domain, which involves predominantly sensitive data—is a high-risk activity because of the possibility of unauthorized leaks and exposure of such data without the data subject's consent.

Alongside intimacy and privacy rights, improper data exposure would taint personal rights and human dignity itself—one of the Brazilian Republic's foundations.

The right to privacy took on new contours with the information society, granting individuals the possibility of knowing, providing, and suspending sharing their personal data through direct consent.

Therefore, in light of the rights to privacy and intimacy, it is possible to affirm that personal data, especially in the health domain—constitute highly personal information capable of identifying and determining their subject, also having political and economic value. When admitting the processing of health-related data, the Public Power must ensure that it is carried out by a duly qualified professional, subject to medical confidentiality or professional health secrecy, with information security measures guaranteed (Caldeira, 2021).

With regard to innovation, digital transformation, and data use, it is necessary to encompass policies on science, technology, and health innovation, as well as socio-economic development policies, without forgetting the legal aspect.

In this path, the General Data Protection Law (LGPD) emerges as a decisive landmark in protecting freedom, privacy, and the individual's position in handling their information as the data subject.

The LGPD's publication was part of a global movement of concern regarding the subject and the role the State must play, inspired by the European Union's General Data Protection Regulation (GDPR).

Regarding scope, the aforementioned law establishes the principles, rights, and duties to be observed henceforth in personal data processing, applying to any personal data processing operation, whether by a natural or legal person, public or private, regardless of the medium, the country of headquarters, or the country where the data are located, establishing rules on collecting, processing, storing, and sharing personal data managed by organizations (Brazil, 2018).

The LGPD, in its Article 5, II, defines sensitive personal data as those relating to racial or ethnic origin, religious conviction, political opinion, union membership or membership in religious, philosophical, or political organizations, data concerning health or sexual life, genetic or biometric data when linked to a natural person (Brazil, 2018).

Consequently, both professionals and institutions involved in processing people's health data need to be mindful of the LGPD's norms to develop and spread a culture of data privacy, through implementing a data security policy to protect individuals' personal and sensitive data and to comply with data subjects' requests.

Specifically in the health area, it is necessary to adapt routines and procedures of medical clinics, both private and public, as well as hospitals, aiming to implement LGPD's provisions—for instance, informing patients (data subjects) about the data submitted for processing, the specific purpose, the retention of records, and the precautions taken to protect such data, since most concern sensitive data.

It is of utmost importance to adopt procedures that prevent data leaks, in addition to defining internal conduct for all collaborators to follow, as well as measures to be taken in case of a leak, which must be periodically updated given the subject's dynamism.

Besides adapting to LGPD—which institutes a culture of respect for data privacy—opt-in and opt-out mechanisms for data use consent by the data subject and requests for data deletion must be available. Furthermore, algorithms must be auditable to guarantee transparency in data processing (especially sensitive data). It should also be emphasized that

the Public Power must foster discussions and debates about AI's purposes and limits in health (Leal-Neto, 2020).

Safer decision-making and the pursuit of maximum possible efficiency using AI will be ensured through compliance with national and international legislation. In this sense, Sousa (2020, p. 44) asserts:

> It is important that coercive normative instruments be developed and applied, representing social and legislative will regarding AI implementation in health in each country, as a result of the principle-based references presented by the framework of health as a right.

Finally, it is worth stressing the need to adopt more elaborate data governance models that combine sustainability and responsibility, aiming to protect and preserve ethical and regulatory principles, thereby ensuring individuals' and society's trust regarding data provision in cases of legitimate public interest, such as health—this underscores "the importance of ongoing debate and effective regulatory policies to ensure responsible AI application in health" (Luar; Oliveira; Fontes, 2024, p. 41).

In this path, despite the privacy right guaranteed in the Brazilian legal system, as well as personal data protection, the use of these data in health would not be impeded when the benefits to civil society are duly proven, as a matter of balancing interests.

4 Ethical and Social Implications of Artificial Intelligence in Health: An Analysis in Light of Fundamental Rights

As previously explained, consolidating AI as an auxiliary instrument in health represents one of the most significant technological innovations of our time, yielding notable advances in diagnostic precision, surgical interventions, treatment expansion, image quality, and optimization of hospital management systems. However, employing such technologies raises complex ethical, legal, and social implications, requiring a critical reflection on the normative and axiological limits that must govern their use—aligned with constitutional principles and fundamental human rights.

From an ethical standpoint, implementing AI systems in clinical decision-making processes necessitates redefining the principle of patient autonomy, which materializes through effective, lucid, and comprehensible informed consent. Faced with the opacity characteristic of machine-learning-based algorithms—whose decision logic may be

inaccessible even to developers themselves—the challenge emerges of reconciling technological innovation with the right to information.

A striking example is IBM's Watson for Oncology system, which was widely promoted as a tool to assist in choosing oncological therapies. Nevertheless, the system suggested inadequate or unrecommended treatments, revealing risks associated with the uncritical adoption of algorithmic solutions in contexts of high clinical complexity (Nelson, 2018). These episodes reinforce the need for constant human oversight and ensuring that patients understand these technologies' limitations.

In this respect, it is worth highlighting that AI use in disease prediction—such as algorithms anticipating malignant neoplasm probability based on biomarkers—requires an ethical governance that ensures both result explainability and confidentiality of the data used.

Law Nº. 13,709/2018—the Brazilian General Data Protection Law—by regulating the processing of sensitive data, including health data, establishes in Article 11 stringent requirements for their collection, use, and storage, making the data subject's explicit and specific consent indispensable, except in legally waived cases.

From a practical perspective, health monitoring apps—like Google Fit or Apple Health—which collect biometric data and user behavioral patterns may, if integrated into clinical databases without appropriate control, generate risk profiles with repercussions on health insurance, transplant selection, or even judicial decisions. This reality demands a profound reflection on ethical limits for automating health data collection, often performed without users' full awareness.

On the normative-legal plane, a guarantee-oriented approach is mandatory, anticipating legal-social consequences of AI use in vulnerable contexts. For example, employing automated clinical triage systems by health insurance providers or in the public sphere may cause indirect discrimination based on biased statistical patterns, disproportionately affecting historically marginalized groups—such as diseases erroneously associated with homosexual individuals, as was the case in earlier HIV campaigns, or prioritizing vaccination in groups without necessity, among others.

Such practices violate not only the principle of equality (art. 5, caput, of the Federal Constitution) but also compromise the effectiveness of the right to health as a social fundamental right, enshrined in article 6 of the Constitution and operationalized via the Unified Health System (SUS), whose pillars are universality, integrality, and equity.

Regarding legal responsibilities arising from AI use in clinical practice, the complex issue of imputing fault in diagnostic or therapeutic errors due to algorithmic failure comes into focus. The traditional configuration of medical civil liability—based on subjective fault analysis (art. 186 and art. 927 of the Civil Code)—must be reconsidered in light of the potential decision-making autonomy granted to AI tools. It is appropriate to open a discussion about adopting an objective liability regime, under comprehensive risk models, in situations where damage predictability is reduced or nonexistent.

An example might occur with an automated system used for radiological image interpretation that fails to correctly identify a case of severe pneumonia, worsening the clinical condition and leading to liability for the healthcare institution. In such a scenario, would liability rest with the algorithm developer, the physician who relied on the automated opinion, or the institution (public or private) that acquired the technology?

Moreover, even partial replacement of medical activity by automated systems undermines medical care's humanization, depleting the empathetic dimension of the doctor-patient relationship. The centrality of the human being in the therapeutic process—corollary of human dignity (art. 1, III, of the Federal Constitution)—cannot be relativized in the name of technical efficiency. Conversely, technology should be understood as an instrument serving dignity, not as a substitute for clinical judgment, which involves sensitivity, listening, and ethical values irreducible to probabilistic calculation.

When automated triage systems replace initial contact with nurses, receptionists, and others, there is an acute risk of urgent cases going undetected, revealing the fragility of an overly technical and dehumanized care approach.

In this regard, one must strive to ensure harmony and consonance with existing health systems in a given jurisdiction, as well as constant monitoring of AI devices used, to mitigate problems related to safety, privacy, responsibility, and reliability of use (Park et al., 2020).

From the foregoing—and to render the study's possible conclusions more didactic and visually perceptible—a table is presented that systematizes the regulatory risks and benefits of AI use in health:

Table 1. Regulatory Benefits and Risks of AI in Healthcare

Regulatory benefits	Regulatory risks
Optimization of health services with faster, more precise, and efficient diagnoses.	Leakage of sensitive data, compromising patient privacy.

Improvement in hospital management and public health policies through big data analysis.	Misuse of personal data without clear and specific consent, violating fundamental rights.
Development of personalized and precision medicine tailored to the patient's genetic and behavioral profile.	Algorithmic discrimination, generating biases that can affect vulnerable groups and reinforce social inequalities.
Increased predictive and preventive capacity in public health (e.g., outbreak and epidemic identification).	Algorithmic failures or errors, potentially leading to incorrect diagnoses and risks to patient health.
Strengthening public governance and efficiency in health-resource use.	Difficulty in legal accountability for errors caused by AI (physician, developer, or institution?).
Support for clinical decision-making, reducing medical errors and optimizing treatments.	Loss of humanization in medical care, reducing patient-professional interaction.
Expanded access to healthcare, especially via telemedicine and remote monitoring.	Risk of non-compliance with ethical, safety, and transparency principles without robust regulation.
Stimulus to scientific and technological innovation in medicine, driving new drug development.	Challenges in sustainability, environmental impacts, and job displacement due to automation without adequate requalification.

In light of this scenario, it is essential to elaborate a specific regulatory framework on AI use in health, guided by transparency, equity, safety, and responsibility criteria. Such regulation must be built with broad democratic participation—involving health professionals, jurists, computer scientists, and civil society representatives—to ensure that technological advances do not deepen inequalities but serve to promote social justice and the effectiveness of fundamental rights.

5 Final Considerations

From this study, it can be concluded that, in the information society era, AI expands its influence to the most diverse areas and individuals, bringing them to the core of technological innovation. However, AI's accelerated expansion and refinement assume that coordinated and

specific actions and measures must be adopted by the Public Power to uphold a culture of data privacy for shared data.

During the Covid-19 pandemic, AI use in health was exponential, spanning diagnosis, therapeutic treatment, medications, patient monitoring, teleconsultations, and even virtual visits to hospitalized patients.

Hence, challenging questions arise on improving AI use in health—AI that can contribute to expanding services and allocating resources more assertively yet must protect individuals' sensitive data in light of privacy principles and society's values enshrined constitutionally.

Despite the ethical-scientific dichotomy between AI use in health and scientific and technological advances, it would not be appropriate to reject these new technological tools but rather to seek legal regulation and carry out more rigorous ethical control, in addition to prioritizing risk management related to individuals' data provided in the health context.

Accordingly, besides incorporating ethical principles to safeguard individuals' privacy and intimacy, it is also necessary to establish safeguards for AI use in the health field, with appropriate amendments to existing legislation to keep pace with constant evolutions.

It is the Public Power's duty to improve existing technologies, aiming for public governance based on responsibility in handling health-related data through specific and oriented public policies.

Nonetheless, it is imperative to emphasize the LGPD's relevance, especially concerning protecting sensitive data, whose processing is regulated in Section II of the said law. Should infractions to LGPD norms occur, data processors are subject to administrative sanctions by the National Data Protection Authority (ANPD), pursuant to Article 52 and its subsections.

Therefore, although some level of data protection and control is observed via the LGPD regulatory framework, particularly after the enactment of the law that transformed the ANPD into a special-nature autarchy (Law No. 14,460/2022), constant improvement in handling sensitive data is required through more stringent measures, creating a more severe core that deserves due safeguarding.

Finally, it is important to stress that, particularly with this study's relevant contributions to the debate on the interface between public governance, AI, and the protection of fundamental rights in the health sector, some limitations restricting its analytical scope must be acknowledged. The main obstacle lies in the predominantly theoretical and normative approach adopted, which, while essential for understanding regulatory frameworks and constitutional principles involved, does not allow for capturing the practical impacts of

AI-based systems implementation in specific contexts of the Unified Health System and its reality within regional public policies.

Moreover, the analysis of privacy protection was based on legal guidelines and constitutional principles, without empirical complement through field data or case studies. In this sense, it is recommended that future research advance in empirical investigation, using qualitative and quantitative studies capable of mapping concrete risks to sensitive data privacy in public health environments and evaluating governance measures' effectiveness. It would also be opportune to explore comparative international experiences to enrich building a Brazilian model of algorithmic regulation that simultaneously promotes technological innovation and safeguards fundamental rights.

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