

The Protection of the Right to Health in the Digital Era: Digital Health, Artificial Intelligence, and Law

*A proteção do direito à saúde na era digital: saúde digital,
inteligência artificial e direito*

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ABSTRACT

The use of digital tools in the governance of health systems and in patient care has become increasingly frequent in the day-to-day functioning of health systems worldwide. This comprehensive set of health products and services that leverage new digital technologies is transforming health systems around the world and establishing digital health as a new and promising field of study, especially due to the enormous potential benefits it can bring to humanity. To understand the emerging challenges related to the regulation of digital technologies relevant to health, the Journal of Health Law has organized this special issue: "Digital Health Law: Regulatory Opportunities and Challenges in Brazil," dedicated exclusively to the dissemination of original scientific articles on the right to digital health and the regulation of artificial intelligence applied to health in Brazil and in other national and multilateral jurisdictions. This issue brings together a series of studies that critically examine digital health, artificial intelligence applied to healthcare, and the effects of digital transformation on health systems, analyzing their impact on fundamental rights and exploring possible regulatory pathways. This special issue aims to contribute to the promotion of a responsible and democratic digital transformation, fully aligned with the foundations, principles, and objectives of the Brazilian National Public Health System, and committed to the realization of the right to health for all individuals.

Keywords: Right to Health; Artificial Intelligence; Digital Health.

RESUMO

No dia a dia dos sistemas de saúde ao redor do mundo é cada vez mais frequente o uso das ferramentas digitais para a governança de sistemas de saúde e o cuidado de pacientes. Esse conjunto abrangente de produtos e serviços de saúde que se utilizam das novas tecnologias digitais está transformando os sistemas de saúde ao redor do mundo e consolidando a saúde digital como um campo de estudo novo e promissor, especialmente devido aos enormes potenciais benefícios que pode trazer à humanidade. Para compreender os desafios que se avizinham no que se refere à regulação das tecnologias digitais de interesse à saúde, a Revista de Direito Sanitário organizou este número especial: "Direito da saúde digital: oportunidades e desafios regulatórios no Brasil", voltado exclusivamente à difusão de artigos científicos originais sobre o direito à saúde digital e a regulação da inteligência artificial aplicada à saúde no Brasil e em outras jurisdições nacionais e multilaterais. O fascículo congrega uma série de estudos que refletem criticamente sobre a saúde digital, a IA aplicada à saúde e os efeitos da transformação digital nos sistemas de saúde, analisando seus impactos sobre os direitos fundamentais e possíveis caminhos regulatórios. Esta edição especial busca contribuir para a promoção de uma transformação digital responsável, democrática, plenamente alinhada aos fundamentos, princípios e objetivos do Sistema Único de Saúde e comprometida com a efetivação do direito à saúde de todas as pessoas.

Palavras-chave: Direito à Saúde; Inteligência Artificial; Saúde Digital.

Conflict of interests:

The authors declare that there is no conflict of interests.

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The authors are responsible for the full development of the article.

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Innovations in modern digital life are revolutionizing the healthcare sector. Massive digital databases are being created and developed to store a wide range of information about individuals, including sensitive health data such as weight, height, heart rate, steps taken, hours of sleep, diet, among others. While these data are stored in large information centers (data centers), their circulation is being facilitated and promoted by global, highly connected digital social networks controlled by major digital corporations. This reality has been increasing the vulnerability of data holders, who lose control over the processing and use of their own sensitive personal information.

In addition, the use of artificial intelligence (AI) applied to healthcare for diagnostic and therapeutic purposes is rapidly expanding. The digital environment is being flooded with technologies that employ AI for purposes related to individual well-being, the promotion, protection, and restoration of health, and therapeutic support across multiple dimensions.

Nowadays, in the daily operations of health systems around the world, the use of digital tools in health system governance and patient care is increasingly common. There are many examples: AI-powered medical equipment capable of performing complex surgeries under human supervision; diagnostic laboratory devices that use digital cloud data and AI to produce conclusive diagnostic reports; massive, organized databases owned by large private corporate groups, with high profit potential through their use (monetization of digital data sets); medical devices capable of conducting anamnesis, providing diagnoses, and even proposing therapeutic plans for patients; management and governance software for public and private healthcare services that organize queues and determine a patient's therapeutic itinerary; internet applications that collect individuals' sensitive data and prescribe behavioral recommendations in the field of physical and mental health.

In summary, AI tools are already being used to track patient data, perform triage, read medical images, diagnose diseases, make treatment decisions, support patients in health promotion, and provide primary, acute, mental, and long-term care. AI innovations will likely not only assist but also, to varying degrees, replace human caregivers, medical service providers, diagnosticians, and specialized decision-makers.

This comprehensive set of health products and services that use new digital technologies is transforming health systems around the world and consolidating digital health as a new and promising field of study, especially due to the enormous potential benefits it may bring to humanity.

However, it is also imperative to recognize that, beyond the benefits these innovations promise, new digital technologies may pose risks to both public and individual health if they are not regulated, monitored, and developed with ethics and responsibility. For this reason, countries must design their own strategies for transitioning into the digital world, and they must strengthen their capacities to understand this transformative phenomenon and to identify priorities and concrete actions necessary for an inclusive digital transformation that serves individuals and society.

One of the essential functions of modern countries is to regulate the health sector comprehensively and thoroughly, with the aim of preventing diseases, promoting and ensuring the right to health, and upholding the fundamental rights recognized in democratic societies. The duty of modern countries to care for both individual and collective health within their territories is enshrined in various international treaties and has been incorporated into national constitutions around the world, with Brazil standing as a prominent example of this global movement (Brasil, 1988, articles 6 and 196 to 200).

There has always been an inherent worldwide tension within health systems between private interests (including private entrepreneurship) and the public interest, which must be safeguarded through appropriate state regulation. This tension has intensified in the field of digital health, especially following the advances made during the COVID-19 pandemic and as a result of the oligopolistic structure of the global digital market.

In the realm of digital health, products and services that make use of artificial intelligence must be regulated by the State to ensure the protection of society. These services, which rely on autonomous or semi-autonomous robots designed for therapeutic care, should be subject to state regulation that both encourages the innovation of socially beneficial products and simultaneously mitigates the risks these technologies may pose to human health and life.

State regulation must be exercised over various aspects, such as: the safety, quality, and effectiveness of digital health technologies and services, and the guarantee of universal access as they are integrated into the health system; requirements for the development, testing, and monitoring of AI algorithms; the protection, storage, and processing of health data, as well as the secondary use of such data for multiple purposes; and criteria for liability in cases of harm caused by AI, among others.

Although some regulatory progress has already been observed at the international level and in certain countries, including Brazil, significant challenges remain in developing and organizing a clear, effective, and coordinated regulatory and institutional environment. Such an environment must provide the necessary foundations for the development of new digital technologies that are beneficial to society and patients, and that respect the fundamental rights of human beings.

To understand the emerging challenges regarding the regulation of digital technologies relevant to health, the *Revista de Direito Sanitário* / Journal of Health Law, published by the *Universidade de São Paulo* (USP), has organized this special issue, dedicated exclusively to the dissemination of original scientific articles on the right to digital health and the regulation of artificial intelligence applied to healthcare in Brazil and in other national and multilateral jurisdictions.

It is with great satisfaction that we present this special issue dedicated to the theme “Digital Health Law: Regulatory Opportunities and Challenges in Brazil.” This edition brings together a series of studies that critically reflect on digital health, AI in healthcare, and the effects of digital transformation on health systems, analyzing their impact on fundamental rights and exploring possible regulatory pathways.

This edition is part of the project “Diagnosing and Analyzing Digital Transformation in Health in Brazil: Current Uses and Regulatory Policies,” funded by the Ministry of Health and developed through a rich partnership between the Center for Research in Health Law at the *Universidade de São Paulo* (Cepedisa/USP), the Center for Bioethics and Health Diplomacy at Fiocruz/Brasília (Nethis/Fiocruz), and the Secretariat for Information and Digital Health of the Ministry of Health (SEIDIGI/MS).

Comprising 16 manuscripts submitted through a public call and reviewed by external ad hoc referees in a double-blind evaluation process, the contributions address, from various perspectives, the intersection of technological innovation, legal regulation, ethics, and the realization of fundamental rights in the era of digital transformation in healthcare.

The texts gathered in this issue show that the regulation of digital health requires an intersectoral and ethical approach, grounded in the principles and guidelines of Brazilian National Public Health System (*Sistema Único de Saúde – SUS*), such as universal access, equitable distribution of resources, comprehensive care, digital inclusion, and respect for human dignity.

Digital health should be understood as the promotion of health actions and services mediated by information and communication technologies, aimed at the protection, recovery, and promotion of health across all levels of care, with its benefits radiating in a universal and equitable manner. We hope this special issue contributes to fostering a responsible and democratic digital transformation, fully aligned with the foundations, principles, and objectives of the Brazilian National Public Health System, and committed to the realization of the right to health for all individuals.

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