Bioethics in contemporary digital medicine

Tatiana Bragança de Azevedo Della Giustina 1.2, Helena Carneiro Leão 3, Giselle Crosara Lettieri Gracindo 4

1. Associação Brasileira de Otorrinolaringologia e Cirurgia Cérvico-Facial, São Paulo/SP, Brasil. 2. Associação Gaúcha de Otorrinolaringologia e Cirurgia Cérvico-Facial, Porto Alegre/RS, Brasil. 3. Academia de Medicina de Pernambuco, Recife/PE, Brasil. 4. Conselho Federal de Medicina, Brasília/DF, Brasil.

Abstract

This is a systematic literature review based on publications available on databases such as PubMed and SciELO. The review aims to analyze some technological advances in Medicine, especially those holding a significant impact on bioethical, regulatory, and legal aspects. Among these new technologies, wearable devices used for continuous patient monitoring, telemedicine and telehealth—which expand access to healthcare for different populations—bioprinting of organs and tissues, and the growing use of artificial intelligence are highlighted. Each of these innovations must be deeply reflected on the regulatory, bioethical, and legal implications involved. Furthermore, it is crucial to analyze their effects on Public Health, the doctorpatient relationship, and the judicialization of healthcare, especially given the high costs associated with them, in a scenario in which financial resources are finite, while social demands are potentially unlimited.

Keywords: Technological advances in health. Public health. Doctor-patient relationship. Judicialization of health.

Resumo

Bioética na medicina digital contemporânea

Este artigo é uma revisão sistemática de publicações disponíveis em bases de dados como PubMed e SciELO com o objetivo de analisar alguns dos inúmeros avanços tecnológicos na área da medicina que geraram grande impacto em aspectos bioéticos, regulatórios e legais. Entre as novas tecnologias, destacam-se os dispositivos vestíveis utilizados para monitoração contínua de pacientes, telemedicina e telessaúde, que ampliam o acesso a cuidados de saúde para diferentes populações, a bioimpressão de órgãos e tecidos, além do uso crescente de inteligência artificial. Cada inovação exige profundas reflexões sobre as repercussões regulatórias, bioéticas e legais envolvidas. Além disso, é fundamental analisar seus efeitos na saúde pública, na relação médico-paciente e na judicialização da saúde, especialmente em razão dos altos custos associados a essas tecnologias para a sociedade, num cenário em que os recursos financeiros são finitos, enquanto as demandas sociais se mostram potencialmente ilimitadas.

Palavras-chave: Avanços tecnológicos em saúde. Saúde pública. Relação médico-paciente. Judicialização da saúde.

Resumen

Bioética en la medicina digital contemporánea

Este artículo realiza una revisión sistemática de la literatura basada en evidencia disponible en las bases de datos PubMed y SciELO, para analizar algunos de los avances tecnológicos en medicina que han generado impactos en aspectos bioéticos, regulatorios y legales. Estas nuevas tecnologías incluyen dispositivos portátiles utilizados para el monitoreo continuo de pacientes, telemedicina y telesalud, que amplían el acceso a la atención médica para diferentes poblaciones, la bioimpresión de órganos y tejidos, y el creciente uso de inteligencia artificial. Cada una de estas innovaciones requiere reflexiones profundas sobre las repercusiones regulatorias, bioéticas y legales involucradas. Además, es fundamental analizar sus efectos en la salud pública, en la relación médico-paciente y en la judicialización de la salud, especialmente por los altos costos asociados a estas tecnologías para la sociedad, en un contexto en que los recursos financieros son finitos, mientras que las demandas sociales son potencialmente ilimitadas.

Palabras clave: Avances tecnológicos en salud. Salud pública. Relación médico-paciente. Judicialización de la salud.

The authors declare no conflict of interest.

Medical practice and science have been transformed over time, generating innovations through new technologies and sparking debates in medicine, philosophy, and law. Bioethics, grounded in the fundamental principles of autonomy, beneficence, non-maleficence, and justice, goes beyond mere theoretical reflection, increasingly establishing itself as an indispensable practice in life, serving as a moral compass. Balancing scientific progress with social justice and equity in access to innovations is essential, while always preserving respect for individual and cultural differences ¹.

New technologies decisively affect diagnosis, treatments (whether surgical or not), prognosis, and the physician-patient relationship. For this reason, regulation and reflection are imperative. In this article, some technological innovations with a major impact on medical practice are analyzed, considering the dynamic nature of the topic and assessing their legal and bioethical aspects, while also contributing to the resolution of the dilemmas they create.

It is important to understand that technologies must ensure, for both patients and physicians, that their use will occur ethically, in accordance with the prerogatives of medical practice, respecting patient rights, and safeguarding their privacy.

Impact of wearable monitoring devices

In terms of technological innovations, wearable devices have gained prominence as they provide real-time data, enabling physicians to manage patients' health more effectively and to track their vital signs, while also supporting other healthcare professionals. Smartwatches and other wearable devices allow for continuous monitoring of patients' vital signs, making it possible for physicians to make precise therapeutic adjustments and prevent potential complications. As a result, these tools render healthcare far more effective and preventive.

Findings indicate that wearable devices and digital health applications enable continuous monitoring, real-time feedback, and personalized care, which can positively influence health outcomes. However, despite their many benefits, they also pose significant challenges. One of the most relevant concerns is data privacy². It is essential to note

that discrepancies in monitoring data may lead to erroneous diagnoses in patients with severely compromised health conditions. For these reasons, it is necessary to develop strategies that ensure proper interpretation of such data, preventing misanalyses and potential risks resulting from inadequate interpretations³.

Telemedicine and telehealth

Telemedicine became definitively incorporated into the daily lives of physicians and patients during the COVID-19 pandemic, due to necessities imposed by that context, highlighting both the benefits and the critical issues of this new model of care. It is undeniable that it has brought numerous conveniences, particularly for remote areas; however, gaps remain concerning the confidentiality of medical information and the quality of the physician-patient relationship within this model.

According to Schramm and Escosteguy⁴, a hasty incorporation of new technologies without bioethical analysis may result in unequal implementation, excluding vulnerable populations due to lack of access. Technologies employing artificial intelligence for diagnostic purposes may generate certain biases, deepening inequalities within specific populations. Furthermore, technologies such as genetic editing and tissue bioprinting may lead to uncoordinated actions between governments and health institutions, even increasing judicialization⁵.

The judicialization of healthcare in Brazil generates significant tension between citizens' rights and the economic sustainability of the Unified Health System (SUS) ⁶. For this reason, integration between the judiciary and the executive powers is crucial to assess the impact of decisions on the health system as a whole. Coordination between the healthcare sector and the judiciary is essential to maximize the benefits and minimize the risks of new technologies.

The absence of physical contact between physicians and patients undoubtedly affects the relationship established, which is fundamental for developing trust and empathy—essential elements for the success of treatments. Moreover, remote consultations may not provide as accurate an

assessment as an in-person physical examination, which could also affect treatment outcomes. In this regard, the Federal Council of Medicine (CFM) Resolution no. 2,314/2022⁷ acknowledges that the gold standard for medical evaluation remains in-person consultation, leaving it to the physician's discretion to determine whether the consultation should be concluded with an in-person examination.

Since telemedicine involves digital platforms, rigorous monitoring of potential privacy violations and control over the misuse of patients' sensitive data are indispensable. The General Data Protection Law (LGPD)⁸ establishes specific guidelines for handling such data, imposing duties of security, consent, and transparency. CFM Resolution No. 2,314/2022⁷ details the proper approach, as do the Brazilian Internet Civil Rights Framework (Law no. 12,965/2014)⁹, the LGPD⁸, and the Telehealth Law (Law no. 14,510/2022)¹⁰.

Bioprinting of organs and tissues

Bioprinting of organs and tissues holds great potential for tissue regeneration and may revolutionize organ transplantation, as the creation of patient-specific organs could drastically reduce dependence on donors and, consequently, shorten waiting lists for such treatments.

From a regulatory and ethical standpoint, it is crucial to assess the safety and effectiveness of this treatment, since, as a recent technology, its long-term effectiveness remains uncertain. According to Oliveira and collaborators ¹¹, guidelines for bioprinting practices are essential to prevent patients from being exposed to the risks of still-experimental procedures, as well as to help limit access due to the high costs associated with this technology. International discussions have also emphasized the need for clear regulatory frameworks and ethical principles for bioprinting, particularly in light of legal uncertainties regarding intellectual property and the safety of these procedures ¹².

Informed consent is essential in this practice, as patients must be fully aware of the limitations and risks of such treatments, thereby upholding one of the fundamental principles of bioethics: autonomy. Decisions must be made consciously,

with complete access to available information, in order to avoid unrealistic expectations ¹.

Artificial intelligence and the autonomy of patients and physicians

Artificial intelligence (AI) has gained increasing visibility and application in healthcare, particularly in personalized diagnoses and treatments, thanks to the vast volume of information it can rapidly process, especially in radiology, oncology, and cardiology. Algorithms analyze and evaluate medical images, detecting abnormalities that might often go unnoticed by a human observer, thus making early diagnosis a reality. In the case of cancer, early detection may mean extended survival or even the cure of the disease.

The most critical issues in this context concern patient privacy and confidentiality, since sensitive information may be exposed, as noted by Elias and collaborators ¹³. Moreover, it is essential to ensure that access to these services does not exacerbate inequalities among patients.

Among the most pressing concerns are the autonomy of both physicians and patients, the secondary role of physicians in establishing diagnoses—which may compromise the physicians' guidance in patients' decision-making, and the lack of clarity regarding liability in cases of medical malpractice. The physician-patient relationship is affected when decisions rely on automated systems ¹⁴.

Assigning responsibility is a highly complex issue in procedures such as robotic surgery, since failures may result either from the surgeon's actions or from the functioning of the software. However, such events are extremely rare when compared to what occurs in traditional surgeries ¹⁵.

In Brazil, there is still no specific legal framework regulating civil liability in cases involving artificial intelligence applied to healthcare. This heightens legal uncertainty in the event of technical failures or harm to patients. A legislative proposal currently under discussion in the National Congress (no. 2,338/2023) ¹⁶ aims to establish a legal framework to regulate the use of Al in the country, which could provide greater predictability and legal protection for professionals and users of these systems.

Final considerations

New health technologies are already transforming medical practice through personalized diagnoses and treatments. Not everything that is scientifically possible is ethically acceptable—the well-known phrase attributed to Van Rensselaer Potter ¹⁷, one of the pioneers of bioethics, encapsulates the concern with scientific and technological advances, particularly in the fields of biology and medicine, and the need to establish ethical limits on their use.

Institutions such as the CFM, which oversees regulation, ethical adjudication, and the development of guidelines, and the regional

councils, which are responsible for oversight and ethical review, must increasingly guide medical practice. Their role is to provide the ethical and bioethical framework that supports a form of medicine capable of embracing technological advances without sacrificing the humanistic dimensions of the physician-patient relationship.

The judicialization of healthcare should be mitigated, given that technological advances may impose significant costs to the system. These impacts must be mitigated through dialogue and coordination between the judiciary and public health authorities, ensuring respect for patients' rights while preserving the sustainability of the public healthcare system.

The authors Tatiana Bragança de Azevedo Della Giustina and Helena Carneiro Leão served as general editors of Revista Bioética. This article is part of the journal's tribute to the 80th anniversary of the Federal Council of Medicine.

Referênces

- 1. Amado TC. Bioética e inovações tecnológicas na saúde: desafios éticos e legais na era da inteligência artificial, bioimpressão e telemedicina. Rev Contemporânea [Internet]. 2024 [acesso 22 jul 2025];4(10):e6358. DOI: 10.56083/RCV4N10-204
- 2. Zhang C, Shahriar H, Riad ABMK. Security and privacy analysis of wearable health device [Internet]. In: IEEE 44th Annual Computers, Software, and Applications Conference (COMPSAC); 13-17 jul 2020; Madrid. 2020 [acesso 22 jul 2025]. Disponível: https://tinyurl.com/26v3m643
- 3. Jacobsen M, Dembek TA, Kobbe G, Gaidzik PW, Heinemann L. Noninvasive continuous monitoring of vital signs with wearables: fit for medical use? J Diabetes Sci Technol [Internet]. 2021 [acesso 22 jul 2025];15(1):34-43. DOI: 10.1177/1932296820904947
- **4.** Schramm FR, Escosteguy CC. Bioética e avaliação tecnológica em saúde. Cad Saúde Pública [Internet]. 2000 [acesso 22 jul 2025];16(4):951-61. DOI: 10.1590/S0102-311X2000000400014
- 5. D'Espíndula TCAS. Judicialização da medicina no acesso a medicamentos: reflexões bioéticas. Rev. bioét. (Impr.) [Internet]. 2013 [acesso 22 jul 2025];21(3):438-47. Disponível: https://tinyurl.com/2wrhywud
- Giustina TBAD. Por que a saúde e a medicina estão na justiça? Porto Alegre: Cidadela; 2018.
- 7. Conselho Federal de Medicina. Resolução CFM nº 2.314, de 20 de abril de 2022. Dispõe sobre a prática da telemedicina no Brasil. Diário Oficial da União [Internet]. Brasília, 22 abr 2022 [acesso 22 jul 2025]. Seção 1. Disponível: https://tinyurl.com/48j7enpt
- 8. Brasil. Lei nº 13.709, de 14 de agosto de 2018. Dispõe sobre a proteção de dados pessoais e altera outras leis (Lei Geral de Proteção de Dados LGPD). Diário Oficial da União [Internet]. Brasília, 15 ago 2018 [acesso 22 jul 2025]. Seção 1. Disponível: https://tinyurl.com/3jt29hpj
- 9. Brasil. Lei nº 12.965, de 23 de abril de 2014. Estabelece princípios, garantias, direitos e deveres para o uso da internet no Brasil (Marco Civil da Internet). Diário Oficial da União [Internet]. Brasília, 24 abr 2014 [acesso 22 jul 2025]. Seção 1. Disponível: https://tinyurl.com/2k4bfear
- 10. Brasil. Lei nº 14.510, de 27 de dezembro de 2022. Altera a Lei nº 12.842, de 10 de julho de 2013, para dispor sobre a prestação de serviços de telessaúde. Diário Oficial da União [Internet]. Brasília, 28 dez 2022 [acesso 22 jul 2025]. Seção 1. Disponível: https://tinyurl.com/5n8mracm

- 11. Oliveira NA, Roballo KCS, Lisboa Neto AFS, Sandini TM, Santos AC, Martins DS *et al*. Bioimpressão e produção de miniórgãos com células-tronco. Pesq Vet Bras [Internet]. 2017 [acesso 22 jul 2025];37(9):1032-9. DOI: 10.1590/S0100-736X2017000900020
- 12. Kirillova A, Bushev S, Abubakirow A, Sukikh G. Bioethical and legal issues in 3D bioprinting. Int J Bioprint [Internet]. 2020 [acesso 22 jul 2025];6(3):272. DOI: 10.18063/ijb.v6i3.272
- 13. Elias MA, Faversani LA, Moreira JAV, Masieiro AV, Bellinati NVC. Inteligência artificial em saúde e implicações bioéticas: uma revisão sistemática. Rev. bioét. (Impr.) [Internet]. 2023 [acesso 22 jul 2025];31(3):1-12. DOI: 10.1590/1983-803420233542PT
- 14. Sauerbrei A, Kerasidou A, Lucivero F, Hallowell N. The impact of artificial intelligence on the person-centred, doctor-patient relationship: some problems and solutions. BMC Med Inform Decis Mak [Internet]. 2023 [acesso 22 jul 2025];23(1):73. DOI: 10.1186/s12911-023-02162-y
- **15.** Oliva A, Grassi S, Vetrugno G, Rossi R, Morte GD, Pinchi V *et al.* Management of medico-legal risks in the digital health era: a scoping review. Front Med [Internet]. 2022 [acesso 22 jul 2025];8:821756. DOI: 10.3389/fmed.2021.821756
- **16.** Brasil. Projeto de Lei nº 2.338, de 2023. Estabelece os fundamentos, os princípios e as diretrizes para o desenvolvimento e a aplicação da inteligência artificial no Brasil. Senado Federal [Internet]. 2023 [acesso 22 jul 2025]. Disponível: https://tinyurl.com/ynwk8yv5
- 17. Potter VR. Bioethics: bridge to the future. Englewood Cliffs: Prentice-Hall, 1971. p. xx. Tradução livre.

Tatiana Bragança de Azevedo Della Giustina - PhD - tatianag.tdg@gmail.com

D 0000-0001-5905-4722

Helena Carneiro Leão - PhD - helena.maria@mppe.mp.br

D 0000-0003-1216-3854

Giselle Crosara Lettieri Gracindo - PhD - gcwallace1@gmail.com

© 0000-0001-5328-4308

Correspondence

Tatiana Bragança de Azevedo Della Giustina – Praça Dom Feliciano, 78, sala 609. CEP 90020-160. Porto Alegre/RS, Brasil.

Participation of the authors

The authors equally participated in the construction of this work.

Editor in charge: Dilza Teresinha Ambrós Ribeiro

Received: 8.4.2025
Revised: 8.8.2025
Approved: 8.12,2025