METACONSENT AND PRIVACY BY DESIGN IN CHALLENGING THE MYTH OF FREE AND INFORMED CHOICE IN TELEMEDICINE

METACONSENTIMENTO E PRIVACY BY DESIGN NO ENFRENTAMENTO DO MITO DA DECISÃO LIVRE E ESCLARECIDA EM TELEMEDICINA

METACONSENTIMIENTO Y PRIVACIDAD DESDE EL DISEÑO PARA DESAFIAR EL MITO DE LA ELECCIÓN LIBRE E INFORMADA EN TELEMEDICINA

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ABSTRACT

This article investigates how patient consent functions as an instrument of therapeutic self-determination in technology-mediated care, focusing on telemedicine in Western countries and in Brazil. It asks whether a privacy by design approach can strengthen what is here called "metaconsent", that is, the patient's informed choice about how their consent is obtained and managed over time. The study adopts a legal-theoretical and transdisciplinary framework, combining civil law theory, medical ethics and insights from behavioral economics, particularly Herbert Simon's notion of bounded rationality and the nudge concept developed by Thaler and Sunstein. Telemedicine is chosen as a case study because of its intensive use of images and sensitive data and its heightened requirements for privacy protection and informational clarity in clinical decision-making. The findings suggest that embedding privacy by design into telemedicine systems enhances metaconsent by increasing transparency, traceability, security and confidentiality and by supporting more intelligible, dialogical and auditable decision architectures. The article concludes that, in telemedical settings, a consistent privacy by design strategy can make metaconsent more robust and more closely aligned with patient autonomy, while still acknowledging the constraints imposed by human cognitive limits and the mediated nature of digital healthcare interactions.

Keywords: Consent, Privacy by Design, Telemedicine, Therapeutic Self-Determination.

RESUMO

A pesquisa investiga a constituição e a efetividade do consentimento voltado à autodeterminação terapêutica do paciente em ambientes assistenciais mediados por tecnologia,

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tendo a telemedicina no mundo ocidental e no Brasil como campo de observação. Procura-se determinar se o modelo de *privacy by design* pode adjuvar para reforçar o metaconsentimento, compreendido como a decisão do paciente acerca da própria dinâmica de manifestação do consentimento. Emprega-se abordagem jurídico-teórica e transdisciplinar, que articula aportes da dogmática civilista, da ética médica e da economia comportamental, com centralidade para a noção de racionalidade limitada em Herbert Simon e para os mecanismos de *nudge* propostos por Thaler e Sunstein. A escolha da telemedicina decorre de suas especificidades no tratamento de imagens e dados sensíveis, bem como das exigências elevadas de proteção da privacidade e de clareza informacional, inclusive para a formação do juízo clínico. Os resultados demonstram que a incorporação de *privacy by design* pode beneficiar o metaconsentimento ao promover transparência, rastreabilidade, segurança e privacidade, além de viabilizar arquiteturas de decisão mais inteligíveis, dialogadas e passíveis de controle. Argumenta-se, por fim, que, no contexto da telemedicina, a aplicação consistente de *privacy by design* favorece para tornar o metaconsentimento mais robusto e alinhado à autonomia do paciente, sem afastar os condicionamentos decorrentes da racionalidade limitada e da mediação tecnológica das relações de cuidado.

Palavras-chave: Autodeterminação Informativa. Consentimento. *Privacy by Design*. Telemedicina.

RESUMEN

Este artículo investiga cómo el consentimiento del paciente funciona como instrumento de autodeterminación terapéutica en la atención mediada por tecnología, centrándose en la telemedicina en países occidentales y en Brasil. Se plantea si un enfoque de privacidad por diseño puede fortalecer lo que aquí se denomina "metaconsentimiento", es decir, la decisión informada del paciente sobre cómo se obtiene y gestiona su consentimiento a lo largo del tiempo. El estudio adopta un marco teórico jurídico y transdisciplinario, que combina la teoría del derecho civil, la ética médica y perspectivas de la economía del comportamiento, en particular la noción de racionalidad limitada de Herbert Simon y el concepto de "nudge" desarrollado por Thaler y Sunstein. Se elige la telemedicina como caso de estudio debido a su uso intensivo de imágenes y datos sensibles, así como a sus exigentes requisitos de protección de la privacidad y claridad informativa en la toma de decisiones clínicas. Los hallazgos sugieren que la integración de la privacidad por diseño en los sistemas de telemedicina mejora el metaconsentimiento al aumentar la transparencia, la trazabilidad, la seguridad y la confidencialidad, y al respaldar arquitecturas de decisión más inteligibles, dialógicas y auditables. El artículo concluye que, en entornos telemédicos, una estrategia consistente de privacidad desde el diseño puede fortalecer el metaconsentimiento y alinearlo mejor con la autonomía del paciente, a la vez que reconoce las limitaciones impuestas por las limitaciones cognitivas humanas y la naturaleza mediada de las interacciones digitales en la atención médica.

Palabras clave: Consentimiento. Privacidad Desde el Diseño. Telemedicina. Autodeterminación Terapéutica.

INTRODUCTION

Telemedicine, by relocating the clinical encounter to digital environments, introduces new elements that shape the construction and expression of the patient's will, with direct implications for the authenticity of therapeutic decisions. As information technologies increase yet another level of complexity to the already delicate exercise of patients' rights to therapeutic self-determination in the doctor–patient relationship, the careful deliberation process that leads to consent becomes even more demanding.

Such consent must comply with the deontological and legal requirements involved, failing when it proves inadequate for its intended purposes. However, as this study both assumes and demonstrates, human rationality is unavoidably limited, and the notion that any deliberative process could be fully free and informed shows itself to be unattainable in practice.

The effective exercise of the right to therapeutic self-determination therefore depends on an expanded understanding that reaches what this article refers to as metaconsent, conceived as the dynamics of choices that precede, transcend, and structure the endogenous act of consenting within the physician–patient relationship, through the acknowledgment of cognitive, informational, emotional, and dialogical constraints. Metaconsent can thus be described as "consent about consent".

On the premise that metaconsent is decisive for ensuring that consent, in the sphere of therapeutic self-determination, can prevail over cognitive and behavioral errors and inducements, this essay investigates whether technical strategies for improving decision-making, embedded from the outset in communication and information systems as a default standard (privacy by design), hold the potential to enhance the effectiveness of these entitlements.

Methodologically, the work adopts a legal-theoretical approach grounded in Brazilian private law doctrine and medical deontology, and unfolds in a transdisciplinary key by incorporating insights from behavioral economics and information technology studies. The theoretical benchmark used to assess, in general terms, this potential is the set of instrumental and protective duties owed to patients, which are ethically and legally affirmed as vectors of fairness presupposed by legal systems in general. In Brazil, these duties are normatively projected from the integrative role of the principle of objective good faith.[3] Accordingly, as an empirical lens for

[3] The concepts of kindness and objective good faith emerge in discussions on interpersonal conduct within legal relationships, yet they originate from distinct normative traditions. The contrast between civil law and common law traditions becomes especially noticeable when viewed side by side. In modern legal and bioethical discussions,

examining the dynamics of choices in healthcare service provision, the article takes telemedicine practice in Western countries and in Brazil as its field of observation, given that it is both rapidly expanding and acutely exposed to ethical and legal dilemmas. the fundamental purpose is to formulate and advance ethical, technical, and regulatory frameworks that orient clinical practice toward enhancing confidence in patients' autonomous therapeutic agency, concurrently ensuring the preservation of their experiential narratives and subjective identities.

TELEHEALTH OR TELEMEDICINE

The Tel Aviv Declaration on responsibilities and ethical norms in the use of Telemedicine, adopted by the 51st World Medical Assembly of the World Medical Association in Israel in October 1999, [4] is an essential point of reference in any examination of deontological standards governing telemedicine. According to the Declaration, telemedicine encompasses medical practice in contexts in which physician and patient are not physically co-located, relying instead on communication tools and information technologies; its scope extends beyond clinical care to include education, research, and health promotion activities, all aimed at

kindness is often regarded as an ethical ideal. In common law countries like the United States, the United Kingdom, Canada, and Australia, professional codes encourage practitioners to act with courtesy, respect, and dignity-especially when dealing with vulnerable individuals. However, this emphasis on kindness remains more of a moral aspiration than a legal requirement. It shapes professional behavior through ethical guidance, but it doesn't carry the force of binding law. Objective good faith, by contrast, is a foundational juridical principle within civil-law systems. Rooted in Treu und Glauben and codified throughout European and Latin American jurisdictions—including the BGB, the Code civil, the Codice Civile, the Portuguese Civil Code, and the Brazilian Civil Code, objective good faith structures the formation, performance, and interpretation of obligations. It gives rise to specific supplementary duties-such as loyalty, cooperation, the obligation to provide information, and the duty of protection-and equips courts with principles to assess conduct that may be exploitative or unfairly opportunistic. Its breach may result in remedies such as damages, the invalidation of contractual clauses, or judicial supplementation of obligations. For the purposes of this study, and considering the distinct normative grammars to which these concepts belong, objective good faith is adopted as a juridical principle with binding normative force, one that shapes the law of obligations and guides the suppression of deviant conduct. AMERICAN MEDICAL ASSOCIATION (AMA). **Code of Medical Ethics**. Chicago: AMA, 2024. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC3399321/. Available at: 10 Dec.2025. CANADIAN MEDICAL ASSOCIATION (CMA). **Code of Ethics and Professionalism.** Ottawa: CMA, 2018. Available at: https://www.cma.ca/cma-code-ethics-and-professionalism. Accessed on: 10 Dec. 2025. GENERAL MEDICAL COUNCIL (GMC). **Good medical practice**. Londres: GMC, 2024. Available at: https://www.gmc-uk.org/professional-standards/good-medical-practice-2024. Accessed on: 10 Dec. 2025. GHESTIN, Jacques. **Traité de droit civil: la formation du contrat.** Paris: LGDJ, 1993. MARTINS-COSTA, Judith. **A boa-fé no direito privado**: critérios para a sua aplicação. 2. ed. São Paulo: Saraiva, 2018. NATIONAL HEALTH SERVICE (NHS). **NHS Constitution for England.** Londres: Department of Health, 2023. Available at: https://www.gov.uk/government/publications/the-nhs-constitution-for-england. Accessed on: 10 Dec. 2025. NOVA, Giorgio de. **La buona fede**. Milano: Giuffrè, 2004.

[4] **WORLD MEDICAL ASSOCIATION.** WMA Declaration of Tel Aviv on responsibilities and ethical norms in the use of Telemedicine. Adopted by the 51st World Medical Assembly, Tel Aviv, Israel, Oct. 1999. Available at: https://www.wma.net/policies-post/wma-declaration-of-tel-aviv-on-responsibilities-and-ethical-norms-in-the-use-of-telemedicine/. Accessed on: 30 Sep. 2025.

reducing distance-related barriers, while upholding in telemedical settings the same ethical and technical standards applicable to in-person medicine, including strict confidentiality of patient data and the requirement of informed consent for medical acts.

Within Western healthcare systems, telemedicine, whose expansion accelerated in the COVID-19 pandemic, has become a permanent model of healthcare delivery and a significant market force, which is here outlined illustratively to underscore the relevance of the proposed investigative approach. The extensive development of health technology infrastructure, comprising telemedicine platforms, remote care facilities, and digital surveillance systems, has been propelled by converging forces: the graying of populations, mounting chronic illness prevalence, and economic pressures to optimize healthcare expenditures, as confirmed by a bibliometric review of global digital-health scientific output between 2019 and 2024, which also indicates, with specific focus on Latin America and Brazil, the consolidation of digital health as a strategic pillar of contemporary health systems. In this landscape, *telemedicine* remains the central keyword in Western countries, closely associated with COVID-19-related terms, while in Latin America the rise of *Mobile Health* and, more recently, the use of artificial intelligence in this domain stands out, with global telehealth research largely concentrated in institutional collaboration networks organized into three major clusters led by Harvard University, the University of London, and German universities, revealing the marked centrality of institutions from high-income countries. [5]

A 2021 survey on the availability of guidelines and training for the provision of telehealth consultations by Allied Health Professionals (AHPs) within the British National Health Service, conducted after the abrupt expansion of this modality during the COVID-19 pandemic, found that, despite relatively frequent (albeit locally issued) regulatory guidance, significant ambiguity persisted, particularly regarding risk management, emergency handling, patient-eligibility criteria, and adaptations for vulnerable groups. The guidance largely focused on technical requirements, software, hardware, and appropriate physical environments, while paying limited attention to defining session length and structuring teleconsultations, especially

[5] CHAGAS, Maria Eulália Vinadé et al. The evolution of digital health: a global, Latin American, and Brazilian bibliometric analysis. **Frontiers in Digital Health**, Lausanne, v. 7, 1582719, 2025. Available at: https://doi.org/10.3389/fdgth.2025.1582719. Accessed on: 9 Dec. 2025. Such study, with the objective of mapping the volume, topics, countries, institutions, and collaboration networks in digital health research, retrieved articles from PubMed, Scopus, and Web of Science, filtering publications from 2019 to November 2024 related to telemedicine/digital health, removing duplicates and excluding editorials, letters, guidelines, retractions, and papers without an abstract.

for patients with disabilities, low digital literacy, or language barriers, and most clinicians reported insufficient training, a situation attributable in part to the absence of uniform national guidelines and to the fragmented production of heterogeneous local norms. [6]

In the United States, several federal and state emergency measures adopted in 2020 have been partially or fully retained: Medicare has permanently broadened coverage for multiple *telehealth* modalities, including video and, in certain circumstances, telephone visits, and continues to update the list of reimbursable billing codes, albeit subject to variation across states and private payers.[7] National-level research drawing on data from 2,135 home health agencies across 48 states, however, shows that, after the surge experienced during the COVID-19 pandemic, telehealth has remained a selectively and often controversially used resource, with some agencies (19%) reducing or discontinuing it on the grounds of technological inadequacy for an older, digitally inexperienced clientele and the lack of dedicated Medicare reimbursement. [8]

A 2022 report by the Inter-American Development Bank assesses the regulatory framework for telemedicine in 26 Latin American and Caribbean countries, Argentina, Bahamas, Barbados, Belize, Bolivia, Brazil, Chile, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Guyana, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, the Dominican Republic, Suriname, Trinidad and Tobago, Uruguay, and Venezuela, aimed at evaluating the coherence of these legal systems with human-rights standards in the telemedicine field. [9]

The forementioned report proposes a seven-dimension telemedicine regulatory-maturity model: (1) regulatory foundations, covering legal definitions, service scope, and practice conditions; (2) telemedicine governance, relating to responsible institutions, planning, and

[6] LEONE, Enza; EDDISON, Nicola; HEALY, Aoife; ROYSE, Carolyn R.; CHOCKALINGAM, Nachiappan. Do UK Allied Health Professionals (AHPs) have sufficient guidelines and training to provide telehealth patient consultations? **Human Resources for Health**, v. 20, n. 82, 2022. DOI: 10.1186/s12960-022-00778-1. Available at: https://doi.org/10.1186/s12960-022-00778-1. Accessed on: 10 Dec. 2025.

[7] GRAND VIEW RESEARCH. Latin America telehealth market size: industry report, 2030. [S. l.], 2024. Available at: https://www.grandviewresearch.com/industry-analysis/latin-america-telehealth-market-report. Accessed on: 9 Dec.2025.

[8] MUKAMEL, Dana B.; SALIBA, Debra; LADD, Heather; CLARK, Melissa A.; ROGERS, Michelle L.; NELSON, Cheryl Meyer; ROCZEN, Marisa L.; SORKIN, Dara H.; ZINN, Jacqueline S.; HUCKFELDT, Peter J. Telehealth use by home health agencies before, during, and after COVID-19. **Health Services Research**, Hoboken, v. 60, n. 5, e14645, 2025. DOI: 10.1111/1475-6773.14645. Available at: https://doi.org/10.1111/1475-6773.14645. Accessed on: 10 Dec. 2025.

[9] AIZENBERG, Marisa. **Regulatory framework for telemedicine: current status and next steps.** Washington, DC: Inter-American Development Bank, 2022. Available at: https://publications.iadb.org/en/regulatory-framework-telemedicine-current-status-and-next-steps\. Accessed on: 9 Dec. 2025.

coordination; (3) personal-data protection, encompassing privacy, security, and confidentiality; (4) technological infrastructure, including interoperability standards, electronic health records, and security requirements; (5) institutional and professional performance, addressing accountability, documentation, and quality of care; (6) patient-centered aspects, such as rights, consent, and information; and (7) cross-cutting principles and human rights, guiding regulation through criteria of equity, non-discrimination, and respect for fundamental guarantees. At the time, it revealed a sharp contrast between countries with relatively sophisticated frameworks, such as Uruguay, Colombia, Peru, Paraguay, and Panama, which have specific statutes defining telemedicine, service scope, and professional responsibilities, and those in an almost pre-normative condition, including Haiti, Suriname, and parts of the Dominican Republic, where telemedicine is not explicitly prohibited but lacks operational guidance; similarly, although Brazil, Argentina, Chile, Colombia, Mexico, Uruguay, and neighboring states have advanced in governance, data protection, technical requirements, and standards for institutions and health teams, most jurisdictions still display thin normative density regarding patient roles and the explicit incorporation of equity, non-discrimination, and vulnerable-group protections, which appear more robustly in Colombia, Panama, Paraguay, Peru, and Uruguay.

Within this assessed landscape, the complexity generated by telemedicine is accentuated by the application of artificial intelligence to mediate healthcare delivery, thereby heightening the risk of human-rights violations. Contemporary ethical debate stresses the need to scrutinize up-to-date international standards and to confront the universalist bias that underpins many of these documents, which are framed around abstract principles such as transparency, accountability, and explainability but often remain insufficiently attentive to global structural asymmetries.

Suliane Motta do Nascimento and co-authors, in a study examining the so considered global normative framework from Organization for Economic Co-operation and Development (OECD) Recommendation on AI (2024), the United Nations Educational, Scientific and Cultural Organization (UNESCO) Recommendation on the Ethics of AI (2021), the World Health Organization (WHO) guidance on AI in health (2021), and the European Commission's High-Level Expert Group Guidelines for Trustworthy AI (2019), identify three analytical axes through which recurrent ethical issues may be captured. The first concerns the promotion of human rights, encompassing dignity, universality, participation, and shared responsibility; the second focuses on risks and harm prevention, including transparency, explainability, data

protection, cybersecurity, and liability for damage; and the third axis, that of social justice, aggregates directives on equity, inclusion, diversity, inequality reduction, and international cooperation. Taken together, these four documents converge around core principles yet differ in granularity and institutional context, and they broadly affirm the need to protect privacy, ensure shared governance and social participation, and advance digital-inclusion policies and international cooperation as safeguards against exclusion and the deepening of inequalities.[10]

The same technical report nonetheless warns that, in peripheral contexts, such guidelines may operate as legitimizing rhetoric for imported technological solutions that leave untouched the inequalities in access, decision-making power, and data protection that shape the everyday lives of patients and health professionals. From this angle, contemporary bioethical critique highlights the "digital coloniality" associated with health-related AI: algorithmic systems designed by large corporations and research centers in the global North are often exported as universal models that disregard local knowledge, national health priorities, and community-based forms of organization, thereby reproducing the pattern denounced by everyday bioethics, in which "ordinary" injustices, such as digital exclusion, opacity of automated decisions, predatory data collection, and technological dependency, are obscured by narratives of efficiency, innovation, and technical neutrality. Telemedicine supported by AI, if not regulated under parameters of social justice and democratic participation, risks turning vulnerable populations into mere data reservoirs and targets of scarcely contestable automated decisions, so that the human-rights legitimacy of technologically mediated healthcare ultimately depends on expanding rather than constraining patient self-determination.

In Brazil, Federal Council of Medicine (CFM) Resolution no. 1.643/2002[11] deontologically defines telemedicine as the practice of medicine carried out through interactive audio-visual and data-communication methodologies, applied to care, education, and research in health, and assigns to the CFM the task of registering legal entities that provide telemedical services. Although electronic health records are neither exclusive to nor strictly necessary for telemedicine, in practice they tend to appear within the same operational context, and CFM

[10] NASCIMENTO, Suliane Motta do; OLIVEIRA, Márcia de; CASSUNDE OLIVEIRA, Dalila; FINKLER, Mirelle; HELLMANN, Fernando; BUSSINGUER, Elda Coelho de Azevedo. Inteligencia artificial, derechos humanos y justicia social: un análisis bioético de las recomendaciones internacionales. **Revista de Bioética y Derecho**, *[S. l.]*, n. 65, p. 82–100, 2025. DOI: 10.1344/rbd2025.65.50275. Available at: https://revistes.ub.edu/index.php/RBD/article/view/50275. Accessed on: 10 Dec. 2025.

[11] **CFM. CONSELHO FEDERAL DE MEDICINA (Brasil).** Resolução CFM nº 1.643, 7 August 2002. Define e disciplina a prestação de serviços através da telemedicina. ***Diário Oficial da União:*** seção 1, Brasília, DF, 26 Aug. 2002.

Resolution no. 1.821/2007[12] regulates the Electronic Patient Record (PEP), conditioning its legal-ethical validity on compliance with technological requirements of security, integrity, and auditability, with detailed criteria set out in the SBIS/CFM Certification Manual for Electronic Health Record Systems. [13]

The multimedia messaging application WhatsApp also frequently arises in discussions of remote medical care. In Opinion no. 14/2017, [14] the CFM classified its use as merely supplementary and unsuitable to replace regulated medical practice or telemedicine, concluding that this and similar tools may support guidance and interaction between physicians and in complementary exchanges with patients, but cannot constitute a complete medical act because the requisite technical and ethical guarantees cannot be ensured; the opinion further requires preservation of patient anonymity so as to avoid exposing identifiable data or images and allows use of the application for confidential communication only within closed professional groups, prohibiting any recreational information-sharing, even among physicians.

[12] CFM. CONSELHO FEDERAL DE MEDICINA (Brasil). **Resolução CFM nº 1.821, 11 de July 2007.** Aprova normas técnicas para digitalização e uso de sistemas informatizados na guarda e manuseio de documentos dos prontuários dos pacientes e dá outras providências. ***Diário Oficial da União***: Seção 1, Brasília, DF, 13 July 2007. Available at: https://sistemas.cfm.org.br/normas/visualizar/resolucoes/BR/2007/1821. Accessed on: 3 Oct. 2025.

[13] The Manual is designated as the official technical reference, available on the CFM and SBIS websites, and medical record systems must ensure: strong authentication and digital signatures using ICP-Brasil certificates; complete audit trails (who did what, when and from where); role-based access control and segregation of duties; encryption at rest and in transit; backup, contingency planning and disaster recovery; time-stamping, version preservation (immutability) and availability; as well as interoperability according to market standards (e.g., HL7/FHIR, TISS, IHE) and privacy/consent policies compatible with the LGPD/Brazil. The Manual also sets out Security Assurance Levels (NGS), ranging from minimum functional requirements (NGS-1) to the level that allows replacement of paper records (NGS-2/NGS-2-N), which requires ICP-Brasil digital signatures and an electronic chain of custody. Software companies and health service providers certified under the Manual may develop, offer, or operate such systems; where associated medical services are provided (e.g., telemedicine or storage of EHRs by a clinic/hospital), registration with the competent Regional Medical Council and appointment of a physician as technical director are required, without prejudice to compliance with information-security rules and the LGPD/Brazil. SOCIEDADE BRASILEIRA DE INFORMÁTICA EM SAÚDE; CONSELHO FEDERAL DE MEDICINA. **Manual de Certificação para Sistemas de Registro Eletrônico em Saúde – SBIS/CFM,** versão 3.0 (e atualizações). São Paulo/Brasília: SBIS/CFM, s.d. Available at: https://www.sbis.org.br e https://portal.cfm.org.br. Accessed on: 3 Oct. 2025.

[14] CONSELHO FEDERAL DE MEDICINA (Brasil). **Parecer CFM nº 14/2017, de 27 April 2017.** Teledermatologia no Sistema Único de Saúde. Brasília, DF, 2017. Available at: https://sistemas.cfm.org.br/normas/pareceres/BR/2017/14. Accessed on: 3 Oct. 2025.

CFM Resolution no. 2.227/2018,[15] which had defined teleconsultation, telesurgery, telediagnosis, teleinterconsultation, and telemonitoring, was revoked before coming into force by CFM Resolution no. 2.228/2019,[16] thereby reinstating Resolution no. 1.643/2002.

Given that data processing covers all operations performed on personal data from collection through storage and deletion, telemedicine necessarily falls within the scope of Brazil's General Data Protection Law (LGPD), [17] which affords particular protection to sensitive data, including health information, and adds an additional layer of care duties toward patients as data subjects, reinforcing the need for good-practice rules and robust data-governance mechanisms.

The COVID-19 pandemic elevated the strategic importance of telemedicine and prompted new action by the CFM to the National Ministry of Health.[18] CFM Letter no. 1756/2020[19] acknowledged the ethical permissibility of expanded telemedicine use during the health emergency—encompassing tele-orientation, telemonitoring, and teleinterconsultation—followed by Ministry of Health Ordinance no. 467/2020, [20] which exceptionally authorized telemedicine under similar parameters and allowed electronic issuance of medical certificates and prescriptions subject to security and authenticity requirements, including electronic signatures backed by ICP-Brasil digital certificates.

CFM Resolution no. 2.314/2022[21] subsequently provided a comprehensive deontological definition and regulation of telemedicine as technology-mediated medical service

[15] CFM. CONSELHO FEDERAL DE MEDICINA (Brasil). **Resolução CFM nº 2.227, 13 December 2018.** Define e disciplina a telemedicina como forma de prestação de serviços médicos mediados por tecnologias. ***Diário Oficial da União:*** seção 1, Brasília, DF, p. 58, 6 Feb. 2019.

[16] CFM. CONSELHO FEDERAL DE MEDICINA (Brasil). **Resolução CFM nº 2.228, 26 February 2019.** Revoga a Resolução CFM nº 2.227/2018 e restabelece a vigência da Resolução CFM nº 1.643/2002. ***Diário Oficial da União***: seção 1, Brasília, DF, p. 91, 6 Mar. 2019.

[17] BRASIL. Lei nº 13.709, 14 August 2018. Lei Geral de Proteção de Dados Pessoais (LGPD). **Diário Oficial da União**: seção 1, Brasília, DF, 15 Aug. 2018. Available at: http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/L13709.htm. Accessed on: 3 Oct. 2025.

[18] **CFM. CONSELHO FEDERAL DE MEDICINA (Brasil).** Ofício CFM nº 1756/2020-Cojur, 19 March 2020. Reconhece, em caráter de excepcionalidade, a possibilidade e a eticidade da utilização da telemedicina durante o enfrentamento do coronavírus. Brasília, DF, 2020.

[19] **MINISTÉRIO DA SAÚDE.** Uso da telemedicina para conter a transmissão do novo coronavírus. 2020. Available at: https://www.gov.br/saude/pt-br/assuntos/noticias/2020/marco/uso-da-telemedicina-para-conter-a-transmissao-do-novo-coronavirus. Accessed on: 30 Sep. 2025.

[20] **BRASIL. Ministério da Saúde.** Portaria nº 467, 20 March 2020. Dispõe, em caráter excepcional e temporário, sobre as ações de telemedicina, com o objetivo de regulamentar e operacionalizar medidas durante a emergência de saúde pública decorrente do coronavírus (COVID-19), em conformidade com a Resolução nº 1.643/2002 e o Ofício CFM nº 1756/2020-Cojur, de 19 March 2020. ***Diário Oficial da União:*** seção 1, Brasília, DF, 23 Mar. 2020.

[21] CONSELHO FEDERAL DE MEDICINA (Brasil). Resolução CFM nº 2.314, 20 April 2022. Define e disciplina a telemedicina como forma de prestação de serviços médicos mediados por tecnologias. **Diário Oficial da União**: seção 1, Brasília, DF, p. 191, 5 May 2022. Available at: https://www.in.gov.br/en/web/dou/-/resolucao-cfm-n-2.314-de-20-de-abril-de-2022-401654948. Accessed on: 3 Oct. 2025.

provision, detailing, among other modalities, remote physician–patient consultation (telemedicine), inter-physician information exchange (teleinterconsultation), remote reporting based on transmitted examinations (telediagnosis), robot-assisted procedures with spatially separated surgeon and patient (telesurgery), remote health-parameter follow-up (telemonitoring or televigilance), initial risk- and symptom-assessment (tele-triage), and advisory interactions between physicians or between physicians and other health professionals (teleconsultancy).

Law no. 14.510/2022[22] establishes the legal framework for telehealth within Brazil's Unified Health System (SUS), setting out principles such as respect for professional autonomy, patient dignity and bodily integrity, confidentiality and secrecy of information, secure data transmission, technical and scientific quality of care, and the preservation of in-person access whenever clinically required, while emphasizing telehealth's integration into both public and private services as a means of reducing regional health inequalities.

More recently, robot-assisted radical prostatectomy, a surgery used to treat prostate cancer within oncological care, has been added to the list of procedures with mandatory coverage by health insurances in Brazil.[23]

In summary, telemedicine today encompasses remote interpretation of tests and images, communication between physicians and patients and among professionals, digital issuance and storage of clinical documents, organized and secure archiving of medical information, and support for therapeutic interventions, including time-critical emergencies, and has become embedded in Western health systems as part of broader strategies for reorganizing care delivery.

If telemedicine advances more quickly than the development of regulations, oversight, and supporting technology, the quality of patient care may decline. Western literature documents risks associated with regulatory gaps, technological weaknesses, and insufficient professional training for virtual practice, showing that unstable connections, uncertified platforms, low-resolution cameras, and interoperability failures may result in incomplete histories, information loss, and diagnostic delays, [24] while in fields such as teledermatology

[22] BRASIL. Lei nº 14.510, de 27 December 2022. Dispõe sobre a prestação de serviços de telessaúde. **Diário Oficial da União**: seção 1, Brasília, DF, 28 Dec.2022. Available at: https://www.planalto.gov.br/ccivil_03/_ato2019-2022/2022/lei/L14510.htm. Accessed on: 3 Oct. 2025.

[23] BRASIL. AGÊNCIA NACIONAL DE SAÚDE (ANS). ANS inclui 1º cirurgia robótica na cobertura obrigatória dos planos de saúde. Consumidor, 05 dez. 2025. Available at: https://www.gov.br/ans/pt-br/assuntos/noticias/beneficiario/ans-inclui-1o-cirurgia-robotica-na-cobertura-obrigatoria-dos-planos-de-saude. Accessed on: 13 Dec. 2025.

[24] LISBOA, Kálita Oliveira; HAJJAR, Ana Clara; SARMENTO, Isabela Perin; SARMENTO, Rebecca Perin; GONÇALVES, Sérgio Henrique Resende. A história da telemedicina no Brasil: desafios e vantagens. **Saúde e Sociedade**, v. 32, n. 1, p. e210170pt, 2023. Available at: https://doi.org/10.1590/S0104-12902022210170pt.

there are reported cases in which poor-quality images or the lack of adequate physical examination have led to underdiagnosis or delayed treatment. [25]

In this scenario, where telemedicine consolidates as permanent infrastructure over uneven regulatory foundations and technological and educational vulnerabilities, consent—purportedly grounded in fully rational deliberation—reveals its inconsistencies and underscores the need for legal protection of patients through critical attention to the very architecture of choices within which consent is formed.

CHOICES, CONSENT, AND METACONSENT IN HEALTHCARE

If consent is not exhausted by mere acquiescence arising from a weakened expression of will, the analytical horizon must be expanded to encompass both consent in the material sense and dimensions that exceed its substantive content, including the dynamic, discursive processes that prepare its formation and the residual effects that persist beyond its most immediate repercussions. It is to this broader outcome of patient self-determination that bioethical and legal discourse alternately refer as informed consent or free and informed consent.

In international bioethics, informed consent is understood as the process by which a competent individual voluntarily determines whether to undergo a medical intervention or participate in research, following the provision of clear, relevant, and sufficient information concerning the procedure's nature, potential risks and benefits, available alternatives, and the right to decline. [26] This concept—consolidated in instruments such as the Nuremberg Code, the

Accessed on: 9 Dec. 2025.

[25] TOMMASINO, Nello; MEGNA, Michele; CACCIAPUOTI, Serena; VILLANI, Angelo; MARTORA, Francesco; RUGGIERO, Andrea; GENCO, Luigi; POTESTIO, Luigi. The past, the present and the future of teledermatology: a narrative review. **Clinical, Cosmetic and Investigational Dermatology,** v. 17, p. 717-723, 21 Mar. 2024. DOI: 10.2147/CCID.S462799. Available at: https://doi.org/10.2147/CCID.S462799\. Accessed on: 9 Dec. 2025. McKOY, Karen; ANTONIOTTI, Nancy M.; ARMSTRONG, April; BASHSHUR, Rashid; BERNARD, James; BERNSTEIN, David; BURDICK, Alan; EDISON, Karen; GOLDYNE, Michael; KOVARIK, Carrie; KRUPINSKI, Elizabeth A.; KVEDAR, Joseph; LARKEY, Janet; LEE-KELTNER, Irene; LIPOFF, Joshua B.; OH, David H.; PAK, Howard; SERALY, Michael P.; SIEGEL, Daniel; TEJASVI, Tejas; WHITED, John. Practice guidelines for teledermatology. **Telemedicine Journal and e-Health**, v. 22, n. 12, p. 981-990, 2016. Available at: https://doi.org/10.1089/tmj.2016.0137\. Accessed on: 9 Dec. 2025. **SOCIEDADE BRASILEIRA DE DERMATOLOGIA.** ***Manual de boas práticas em teledermatologia.*** Rio de Janeiro: SBD, 2022. Available at: https://www.sbd.org.br/fileadmin/user_upload/manual-de-boas-praticas-em-teledermatologia.pdf. Accessed on: 3 Oct. 2025.

[26] DEPARTMENT OF BIOETHICS & HUMANITIES. Informed consent. Seattle: University of Washington, [s.d.]. Available at: https://depts.washington.edu/bhdept/search/node/informed%20consent. Accessed on: 9 Dec.2025. FADEN, Ruth; BEAUCHAMP, Tom; KING, Nancy. Informed consent. In: ZALTA, Edward N. (ed.). Stanford

Declaration of Helsinki, the Council for International Organizations of Medical Sciences (CIOMS) Guidelines, and the International Covenant on Civil and Political Rights[27] —marks the transition from a paternalistic medical model to an ethics of self-determination, serving in clinical bioethics as a practical expression of the autonomy principle and, in Anglo-American medical law, as a legal duty whose breach may ground civil liability. [28]

In French medical and legal tradition, consentement libre et éclairé recognizes that meaningful consent rests on two interconnected pillars: the freedom to make one's own choices without being pressured or manipulated, and the ability to truly understand what's at stake, which depends on receiving information that's not only complete and clear but also adapted to how each individual thinks and processes information. Medical-ethics texts in this tradition describe *consentement libre et éclairé* as a dialogical process initiated through explanations about the object, methods, risks, benefits, alternatives, and foreseeable consequences, and characterize it as the "cornerstone" of dignity, bodily integrity, and autonomy protection in both therapeutic and research contexts. [29]

Brazilian bioethics and regulation tend to adopt this Francophone matrix by enshrining the expression "*consentimento livre e esclarecido"*. In broad terms, *informed consent* is often portrayed as a subjective right to information and a safeguard against unauthorized interventions, whereas *consentement libre et éclairé* figures as a relational, ongoing, and contextual process, suggesting that the Francophone tradition places greater emphasis on communicative quality, adaptive information, and the social dimension of decision-making, while the Anglo-Saxon tradition, at least in theory, underscores the formal structure of information.

Encyclopedia of Philosophy. Stanford: Stanford University, 2017. Available at: https://plato.stanford.edu/search/searcher.py?query=informed+consent. Accessed on: 9 Dec. 2025.

[27] COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES; WORLD HEALTH ORGANIZATION. Diretrizes éticas internacionais para pesquisas relacionadas à saúde envolvendo seres humanos. Genebra: CIOMS/OMS, 2016. Available at: https://cioms.ch/wp-content/uploads/2018/11/CIOMS-final-Diretrizes-Eticas-Internacionais-Out18.pdf. Accessed on: 9 Dec. 2025.

[28] CARVALHO, Rayanna Silva; LIMA, Éfren Paulo Porfírio de Sá. Análise da estrutura dogmática do consentimento livre e esclarecido na pesquisa com seres humanos. **Civilistica.com**, Rio de Janeiro, v. 12, n. 1, p. 1–38, 2023. Available at: https://civilistica.emnuvens.com.br/redc/article/view/829. Accessed on: 9 Dec.2025.

[29] NEILSON, Grainne; CHAIMOWITZ, Gary. Le consentement libre et éclairé aux soins en psychiatrie. **Canadian Journal of Psychiatry** / Revue canadienne de psychiatrie, v. 60, n. 4, p. 1-12, 2015. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4459250/. Acesso em 9 Dec.2025. DESPRÈS, Caroline. Paradoxes du consentement éclairé en sciences humaines et sociales. The paradox of informed consent in social science and humanities. [S.l.]: Elsevier, 2020. Available at: https://www.sciencedirect.com/science/article/abs/pii/S1636652220301586. Accessed on: 9 Dec.2025.

Ana Cláudia S. Barcellos, for example, in discussing *consentimento esclarecido* in bioethics, stresses that the qualifier *esclarecido* shifts the focus from a mere duty to inform toward an obligation to render information intelligible for that specific patient in his or her concrete circumstances. [30]

CFM Recommendation no. 1/2016[31] sets out guidance for the process of obtaining free and informed consent in medical care, defining consent as the decision of the patient—or legal representative—taken after receiving necessary and appropriate information from the physician regarding diagnostic or therapeutic procedures, with the aim of promoting freedom of choice and absence of defects. In principle, the physician must explain justifications, expected objectives, benefits, risks, side effects, complications, duration, required care, and other procedure-specific aspects, using accessible language and actively encouraging questions. The document conceptualizes an ideal consent unfolding in three phases that correspond, respectively, to initial elements, informational content, and comprehension; in the first phase, the professional is expected to create an environment in which the patient can understand and decide voluntarily, thereby exercising therapeutic self-determination.

This aspirational standard is reinforced by Brazilian legislation[32] that sets principles, guidelines, and rules for research involving human beings within public or private institutions and creates the National System of Ethics in Human Research, defining free and informed consent as a manifestation, typically in writing, that records the person's voluntary decision to participate in research after having been duly informed and enlightened about all aspects relevant to the decision.[33]

Even where there is acknowledged theoretical consensus regarding the limitations of consent conceived purely as the expression of a fully conscious reason, a significant strand of scholarship continues to presuppose a notion of private autonomy that is free from direct

[30] BARCELLOS, Ana Cláudia S. O consentimento esclarecido em matéria de bioética. **Revista da Faculdade de Direito da Universidade de São Paulo,** São Paulo, v. 104, p. 493-521, 2009. Available at: https://revistas.usp.br/rfdusp/article/view/67868. Accessed on: 10 Dec.2025.

[31] CFM. CONSELHO FEDERAL DE MEDICINA (Brasil). **Recomendação CFM nº 1/2016 – Processo de obtenção de consentimento livre e esclarecido na assistência médica**. Brasília, DF: CFM, 21 2016. Available at: https://portal.cfm.org.br/images/Recomendacoes/1_2016.pdf. Accessed on: 4 Oct. 2025.

[32] BRASIL. Lei nº 14.874, de 18 March 2024. Dispõe sobre a pesquisa com seres humanos e institui o Sistema Nacional de Ética em Pesquisa com Seres Humanos. **Diário Oficial da União**, Brasília, 2024. Available at: https://www.planalto.gov.br/ccivil_03/_ato2023-2026/2024/lei/l14874.htm. Accessed on: 28 Sep. 2025.

[33] Brazilian data protection law similarly conceptualizes consent as presupposing full rational capacity, framing it as a free, informed, and unequivocal expression by which the data subject authorizes the processing of their personal data for a clearly defined purpose. BRASIL. Lei nº 13.709, 14 August 2018. Lei Geral de Proteção de Dados Pessoais (LGPD). **Diário Oficial da União**: seção 1, Brasília, DF, 15 Aug. 2018. Available at: http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/L13709.htm. Accessed on: 3 Oct. 2025.

external constraints on the outward manifestation of will.[34] Necessary medical information is thus framed as that which enables a conscious decision in light of the patient's own values, [35] though persistent uncertainty remains regarding adequate information volume, linguistic intelligibility, and the measurability of individual awareness.

There is undeniable merit in this theoretical-normative construct in repositioning the patient within the relational field of healthcare. Consent indeed functions as an element that valorizes patient autonomy and signals a move beyond an overtly paternalistic model, with information as its very foundation. [36]

The difficulty, however, lies in human fallibility in the face of totalizing and abstract tasks.

As Flaviana Rampazzo Soares notes, [37] multiple and heterogeneous biases affect medical performance, reflecting behavioral patterns shaped by internal convictions and external factors and requiring professionals to remain vigilant and proactive in mitigating risks to valid consent and sound clinical judgment, always accounting for concrete circumstances in tailoring individualized responses.

This gives rise to questions about the information to be provided to patients under requirements of correctness, completeness, and intelligibility: is it plausible to expect that, particularly in highly vulnerable physician–patient contexts, the professional can fully bracket personal values and avoid distortions? Is it reasonable to assume that individuals, physicians or patients, can possess full awareness of all their own cognitive biases?

Brazilian authors who reject the term "informed consent" in favor of "free and informed consent" often seem to presuppose a consent rendered under full rationality, in which understanding would be complete and biases overcome through linguistic refinement alone.[38]

[34] SÁ, Maria de Fátima Freire de; NAVES, Bruno Torquato de Oliveira. *Bioética e biodireito*. 7. ed. Indaiatuba, SP: Editora Foco, 2025, p. 15.
[35] MALUF, Adriana Caldas do Rego Freitas Dabus. **Curso de bioética e biodireito.** 4. ed. São Paulo: Almedina, 2020, p. 420.
[36] MEIRELES ARAÚJO, Ana Thereza; LINS-KUSTERER, Liliane; VERDIVAL, Rafael. Vulnerabilidade e compreensão como fundamentos do consentimento na relação médico-paciente. **Revista Brasileira de Direito Civil**, *[S. l.]*, v. 31, n. 01, p. 275-295, 2022. Available at: https://rbdcivil.ibdcivil.org.br/rbdc/article/view/735. Accessed on: 4 Oct. 2025, p. 276.
[37] SOARES, Flaviana Rampazzo. **Consentimento do paciente no direito médico** [e-book]: validade, interpretação e responsabilidade. Indaiatuba, SP: Editora Foco, 2021, p. 14..
[38] **GOGLIANO, Daisy Giuliani.** O consentimento esclarecido em matéria de bioética: ilusão de exclusão de responsabilidade. ***Revista da Faculdade de Direito da Universidade de São Paulo,*** v. 104, p. 509-547, Jan./Dec. 2009. Available at: https://revistas.usp.br/rfdusp/article/view/67868. Accessed on: 10 Dec. 2025.
ZILIO, Daniela. O consentimento livre e esclarecido e o direito à informação na relação médico-paciente: a construção da autonomia para decidir. **Revista Brasileira de Direitos e Garantias Fundamentais**, Florianopolis,

Confronted with inescapable bounded rationality and contemporary technological complexity, however, what proves more consequential than substituting labels is a temporal-spatial shift in focus: away from the final content of the decision and toward the architecture and procedure of choice, with emphasis on gradual clarification processes, less deceptive interface design, review mechanisms, and the manner of consenting itself. Looking at it this way, truly protecting a patient's ability to decide for themselves goes beyond just checking boxes or using the right terminology. It requires creating solid institutional frameworks, fostering genuine communication, and developing dependable technologies that shape how we actually ask for and receive consent.

Herbert Simon's[39] debates on the idea of perfect rationality, represented by the homo economicus, highlight something that is often overlooked: human thinking tends to operate within cognitive boundaries, which casts doubt on the premise that people make decisions with all the information they need. In fact, preferences do not emerge from an integral analytical framework. Rather, decisions are evidently distant from perfect optimization, understood as a utopian goal. In conclusion, decision-making is only feasible outside strict optimization, as individuals employ heuristics[40] and satisficing strategies, filtering alternatives that sufficiently meet their purposes while taking into account the concrete realities and limitations of their experiences.

In later work, Simon[41] reframes *bounded rationality* in positive analytic terms, observing that traditional economics concentrates on outcomes—products of reasoning—while neglecting decision-making processes; [42] his notion of procedural rationality highlights the

Brasil, v. 10, n. 1, 2024. Available at: https://www.indexlaw.org/index.php/garantiasfundamentais/article/view/10358. Accessed on: 10 Dec. 2025.

[39] SIMON, Herbert A. A Behavioral Model of Rational Choice. **Quarterly Journal of Economics**, v. 69, n. 1, p. 99-118, 1955.

40 Heuristics can be understood as simplification operations that assist in managing complex tasks, but which might produce systematic errors. TVERSKY, Amos; KAHNEMAN, Daniel. Judgment under uncertainty: heuristics and biases. **Science**, v. 185, n. 4157, p. 1124-1131, 1974. Available at: https://www.science.org/doi/10.1126/science.185.4157.1124. Accessed on: 13 Dec. 2025.

[41] SIMON, Herbert A. *Rationality as Process and as Product of Thought*. ***American Economic Review***, v. 68, n. 2, p. 1-16, 1978.

[42] SIMON, Herbert A. From substantive to procedural rationality. In: KASTELEIN, T. J.; KUIPERS, S. K.; NIJENHUIS, W. A.; WAGENAAR, G. R. (org.). **25 years of economic theory.** Boston: Springer, 1976. p. 129 a 148. DOI: 10.1007/978-1-4613-4367-7_6. Available at: https://doi.org/10.1007/978-1-4613-4367-7_6. Accessed on: 9 Dec. 2025.According to Barros (2016), when addressing bounded rationality, Simon initially shows concern solely with the outcome of the decision-making process, which is embodied in the choice that motivates deliberative dynamics, designating it as substantive rationality. Already in the 1970s, he emphasizes that, in complex situations, this outcome is strongly influenced by the decision-making process itself. He thus infers that knowing which decision is made is as relevant as knowing how it is made, since, as Simon states (p. 131), "behavior is procedurally rational when it is the result of an appropriate deliberative process." BARROS, Gustavo. **Racionalidade e organizações:** um estudo sobre comportamento econômico na obra de Hebert A. Simon. São Paulo: Ed. do Autor, 2016, p. 97.

understanding and consideration of effective search and decision-making methods and procedures. Consequently, decisions are generated based on partial information and deliberate simplifications of reality (heuristics).

Biases often operate beyond the threshold of full conscious awareness, and physicians may neither recognize their presence nor exercise complete control over their influence. Within this horizon, metaconsent[43] becomes as important as consent itself. The term designates the procedural dimension of consent, necessarily interwoven with bounded rationality: metaconsent precedes and outlives the consenting act, addressing the way consent is obtained and conducted and the authorship of the exogenous choice architecture.[44]

In other words, metaconsent is the deliberative act concerning the expanded and dynamic framework within which consent is produced, in other words, a "consent about consent." Metaconsent encompasses the patient's decision to navigate pathways and adopt cognitive and deliberative models that are known to be risky, biased, and inherently limited.

In telemedicine, patients are required to consent not only to medical procedures but also to their own limitations and to the inherent risks associated with information technologies. Particular attention must be given to the necessity for patients to understand and choose to exercise therapeutic self-determination through channels that may themselves be compromised by the very nature of certain specialties, whose examination, diagnosis, and treatment ordinarily require intimacy-sharing, high-definition imagery, and, in many cases, in-person encounters.

The telemedical physician–patient relationship thus involves, on one side, a layperson in technical terms and, on the other, a professional who masters the means of providing healthcare, with the patient also acting as a user of the digital platform through which services are delivered and as the decision-maker who selects among proposed options according to personal knowledge and available information.

[43] The prefix meta derives from the Greek μετά (metá), which means "between, with, after, beyond." In philosophy and in the sciences, it usually denotes a second-order reflexivity, that is, something that stands "about X" or that reflects "upon itself" (for example, metalanguage = language about language). PRIBERAM. Dicionário Online Priberam da Língua Portuguesa. Entry: "meta-". Available at: https://dicionario.priberam.org/meta . Accessed on: 08 Oct. 2025.

[44] The notion of metaconsent developed in this study is not the same as that used, according to Ploug and Holm, in the context of European bioethics. For these authors, meta consent designates an ethical and procedural model aimed at refining informed consent in biomedical research, especially for the secondary use of health data; unlike broad consent, which generally authorizes future uses of data, metaconsent allows data subjects to define in advance the circumstances under which they eventually authorize the reuse of their information. PLOUG, Thomas; HOLM, Søren. Meta consent – a flexible solution to the problem of secondary use of health data. **Bioethics**, v. 30, n. 9, p. 721-732, 2016. Available at: https://doi.org/10.1111/bioe.12286. Accessed on: 8 Oct. 2025.

Consent and metaconsent are formed within a context of intersubjectivity, which is especially evident where legal and deontological commands assign correlated duties that presuppose dialogue and mutual understanding.

Good faith,[45] understood as a general-clause normconcretized through case-by-case application, [46] aims at protecting legitimate expectations[47] and ensuring that the material circumstances of factual-juridical situations prevail.[48]

If the decisional process underlying consent must incorporate the broader panorama of metaconsent, then information must extend beyond the medical object itself to encompass the procedures and formats through which choices are framed and guided. This raises the question whether behavioral strategies embedded from the design phase into information and communication systems (*privacy by design*) can enhance the effectiveness of exercising the entitlements at stake.

PRIVACY BY DESIGN

In every domain of life, including healthcare, decisions must be made: patients have to weigh the risks and benefits of a proposed treatment in order ultimately to accept or refuse it, and further decisions concern the very architecture of choices itself, captured here under the notion of metaconsent.

[45] Judith Martins-Costa explains more broadly that the three functions of objective good faith may overlap in a single contractual situation. However, they remain three distinct functions, which in practice can be very similar, especially the hermeneutic and integrative functions; even if they do overlap in actual circumstances—for example, when interpreting a contract or integrating it by identifying a duty, the solution adopted may at the same time correct the contract's content or a party's conduct—on the analytical and functional plane, the creation of duties through integration of contractual content is not the same as the corrective function applied to that content. MARTINS-COSTA, Judith. **A boa-fé no direito privado**: critérios para a sua aplicação. 2. ed. São Paulo: Saraiva, 2018, p. 240 e 241. O termo "in concreto" é isso mesmo? Se for, não deveria estar em itálico, referindo-se ao termo em latim?

[46] Subjective good faith, in turn, may be defined as a psychological state structured around an inner, mental element, and therefore closely related to the particular situation and individual worldview of a specific, context-bound person. CORDEIRO, Antônio Manuel da Rocha e Menezes. **Da boa fé no direito civil**. Coimbra: Almedina, 2007.

[47] BRASIL. Código Civil: Lei nº 10.406, 10 January 2002. Institui o Código Civil. **Diário Oficial da União**: Brasília, DF, 11 Jan. 2002. Available at: http://www.planalto.gov.br/ccivil_03/leis/2002/l10406.htm . Accessed on: 4 Oct. 2025.

[48] Within what has come to be understood as objective good faith in contract law, three functions stand out: interpretative, control, and integrative. In its interpretative function, good faith protects contractual trust by seeking, through interpretation, not what the parties subjectively intended, but what is reasonably expected to be achieved in a reliable contractual relationship; in its control function, good faith operates as a check on the exercise of rights, aiming to prevent abusive conduct; finally, in its integrative function, good faith introduces ancillary duties into the contract, such as the duty to inform in contractual relations. BIZELLI, Rafael Ferreira. **Contrato Existencial: evolução dos modelos contratuais**. Rio de Janeiro: Lumen Iuris, 2018.

Therapeutic self-determination involves complex choices, and the configuration of the dynamics that precede, traverse, and outlast consent defines the intersubjective, technological, and care context in which information is received—always in incomplete form—as well as the limited human capacity to apprehend and process such informational content.

As seen, decision-making, from the standpoint of behavioral economics—especially when considering cognitive biases and the boundaries of human rationality—has arisen as a significant focus of contemporary economic scrutiny.[49]

Thaler and Sunstein[50] share the idea of bounded rationality and employ the term *homo economicus* to describe the hypothetical agent constructed by economic theory who, in decision-making, always reflects sufficiently and invariably chooses correctly; in contrast, they invoke *homo sapiens* to refer to real people who, in most situations, struggle to choose in the face of a complex world.

Beyond bounded rationality, the drive to maximize gains takes place in a relativized reality in which only some alternatives are actually considered, so the task is not to identify the objectively most efficient option but to search among the options one can see and deems convenient, such that choice-simplification itself constrains rationality.[51]

Daniel Kahneman,[52] in turn, posits that the human mind operates through two systems of thinking, labelled system 1 and system 2: system 1 functions rapidly and automatically, with little or no effort and outside voluntary control, whereas system 2 requires more time and sustained attention to perform more complex mental activities. Heuristics—shortcuts that simplify reality—are rooted in system 1 and rely more on intuitions than on probabilities, which can result in biased interpretations and choices grounded in inconsistent factual assessments.

Every decision is therefore shaped by an "architecture of choices" that is subjectively apprehended and influenced by a variety of agents who may or may not benefit, intentionally or otherwise, from the selected alternatives, while exogenous stimuli frequently steer decision processes either toward systematic errors (biases) or, conversely, toward outcomes more closely

[49] BAZERMAN, Max H. **Processo decisório**. Rio de Janeiro: Elsevier, 2014. SUNSTEIN, Cass R.; THALER, Richard H. O paternalismo libertário não é uma contradição em termos. Civilistica.com. **Revista eletrônica de direito civil**. Rio de Janeiro: a. 4, n. 2, 2015, p. 1-47. Available at: https://civilistica.emnuvens.com.br/redc/article/view/600. Accessed on: 4 Oct. 2025.
[50] THALER, Richard H.; SUNSTEIN, Cass R. **Nudge:** como tomar melhores decisões sobre saúde, dinheiro e felicidade. Rio de Janeiro: Objetiva, 2019.
[51] BARROS, Gustavo. **Racionalidade e organizações:** um estudo sobre comportamento econômico na obra de Hebert A. Simon. São Paulo: Ed. do Autor, 2016, p. 65-67.
[52] KAHNEMAN, Daniel. **Rápido e devagar**: duas formas de pensar. Rio de Janeiro: Objetiva, 2012.

aligned with the decision-maker's own preferences, without eliminating freedom of choice; this gentle "push," which does not amount to a duty or obligation, is the light form of inducement that Thaler and Sunstein call a *nudge*.[53]

In telemedicine, *nudges* can be useful tools for securing consent and, especially, metaconsent, by structuring the choice architecture in ways that support procedural rationality.

Heuristic resources may help to avoid systematic errors or biases in defining clinical pathways, particularly when they broaden the decision-maker's perspective and enable active participation and awareness regarding how the choice architecture itself is configured, thereby allowing the patient to consent to that structure as well—metaconsent within therapeutic self-determination.

Whether *privacy by design* can contribute to this aim is a key question. Conceived originally outside law and economics, it nonetheless has potential influence on decision-making; Ann Cavoukian[54] argues, in the context of public- and private-sector service provision, that the development of information technology and large-scale data collection compels renewed reflection on suitable mechanisms for privacy protection, historically tied to legal rules and regulatory structures, and maintains that essential freedoms depend on preserving data-subject control over personal information, challenging the fallacy that achieving adequate security requires sacrificing privacy in a supposed zero-sum trade-off.[55] In her proposals, *privacy by design*, or "privacy from inception", emerges as a strategy for cooperatively and solidaristically strengthening privacy and trust, including through the refinement of appropriate technologies.

Cavoukian sets out seven foundational principles of *privacy by design*,[56] grounded in the conviction that data-processing organizations should act proactively, preventing violations rather than merely reacting to them; she advocates privacy as the default setting (*privacy by default*), meaning that systems and services ought to follow standard configurations that afford

[53] THALER, Richard H.; SUNSTEIN, Cass R. **Nudge:** como tomar melhores decisões sobre saúde, dinheiro e felicidade. Rio de Janeiro: Objetiva, 2019.
[54] CAVOUKIAN, Ann. Privacy by design: the definitive workshop. A foreword by Ann Cavoukian, Ph.D. **Identity in the Information Society,** Aug 2010, Volume 3, Issue 2, pp 247-251. Available at: https://link.springer.com/content/pdf/10.1007%2Fs12394-010-0062-y.pdf. Accessed on: 30 Mar. 2025.
[55] CAVOUKIAN, Ann. Operationalizing Privacy by Design. A guide to implementing strong privacy practices. **Information & Privacy Commissioner**: Toronto, 2012, p. 248. Available at: https://gpsbydesigncentre.com/wp-content/uploads/2021/08/Doc-5-Operationalizing-pbd-guide.pdf. Accessed on: 30 Mar. 2025.
[56] CAVOUKIAN, Ann. Privacy by design. The seven foundational principles. **Implementation and mapping of fair information practices**. Toronto: Privacybydesign, 2011. Available at: https://www.privacysecurityacademy.com/wp-content/uploads/2020/08/PbD-Principles-and-Mapping.pdf. Accessed on: 30 Mar. 2025.

a high degree of security, and she further recommends embedding privacy into the design of information-technology architectures and related practices, prudently reconciling the interests of data controllers and data subjects without unnecessary concessions, treating *privacy by design* mechanisms as both the prelude and the epilogue of interactions involving personal data, and committing to auditable transparency and to the concrete, robust measures—such as accessible notices and intuitive options—that enable full exercise of data-subject rights.

Privacy by design and *nudges* are not conceptually identical, but they can be combined in practice: the former operates as a system-design paradigm oriented toward data protection, within which the latter may function as specific choice-architecture strategies that steer users toward more privacy-protective decisions—for example, protective default settings, clear warnings, and salient opt-out options that enhance the effectiveness of *privacy by design* and guide user choices.

Where the technological apparatus of telemedicine amplifies the risk of violating patients' authentic self-determination rights, the premises of *privacy by design* thus appear particularly suited to fostering *nudges* that support more effective therapeutic self-determination.

PRIVACY BY DESIGN AND METACONSENT EFFECTIVENESS IN TELEMEDICINE

Metaconsent in telemedicine, in light of the foregoing discussion, appears capable of benefiting from the toolkit derived from *privacy by design*.

The analysis identifies at least three broad classes of strategies aimed at enhancing the effectiveness of metaconsent in therapeutic self-determination within technology-mediated environments.

Within the sphere of behavioral and cognitive safeguards, clinical deliberation must proceed on the premise that physician and patient always dialogue, exchange information, and assess options under conditions of limited communication, limited predictive capacity, and incomplete calculation of consequences; metaconsent encompasses choices relating to the very process of consenting in the exercise of therapeutic self-determination, such that the identity traits, technical training, and bounded rationality of those who conduct and participate in the process—elements inseparable from the structuring of the choice architecture—should be made

explicit and shared. In this sense, clear and empathetic language should be pursued as far as possible, and all actors must remain attentive to multiple contextual vulnerabilities that extend beyond the decision-maker alone.

On the technological plane, the adoption, quality, purpose, and risks of tools—both for privacy and for the specific scope of health care—must be the object of explicit information and deliberation, including the choice and qualification of the digital platform (for example, at NGS2 level) and its interoperability with the Electronic Health Record system when applicable. Authentication and auditability should be carefully weighed and, where not detailed, should be favored by those who articulate the decision variables; minimum technical standards for communication and image quality as conditions for diagnosis can form part of the preparatory process for therapeutic self-determination, alongside consideration of alternatives such as synchronous sessions, support from a family member, authorized recording, or substitution by in-person care.

From the legal and ethical-deontological perspective, the relevant legal and regulatory guidelines, good-practice recommendations, data-governance parameters, and broader telehealth protocols must be observed, [57] including proper documentation in physical or electronic medical records and robust transparency and accountability consistent with duties of care, loyalty, and security.

Recognizing that metaconsent, or reflective consent, precedes, accompanies, and follows the specific deliberation on therapeutic self-determination, *privacy by design* can function as a key instrument for its materialization, insofar as its mechanisms promote proactive postures and preventive configurations in computational systems and data-processing policies, with technological infrastructures prepared from the outset to meet satisfactory security standards; these mechanisms can operate throughout the full extent of metaconsent, facilitating preference configuration, fostering engagement with transparency, enabling monitoring, and providing simplified channels for patients to exercise their rights.

[57] The U.S. HIPAA statute (Health Insurance Portability and Accountability Act of 1996) is an international reference point for health-care compliance, particularly because it establishes standards for encryption, access control, and traceability of medical data. Although a foreign instrument, its influence is recognized in Brazilian legal scholarship and hospital policies, which adapt its technical-security guidelines to the national regulatory environment. In the same vein, the aforementioned "Manual de boas práticas em teledermatologia" from the Brazilian Society of Dermatology likewise reinforces guidelines derived from that document. ESTADOS UNIDOS DA AMÉRICA. Health Insurance Portability and Accountability Act (HIPAA). Public Law 104–191, 1996.

CONCLUSION

Consent, in its forms of assent and informed choice, does not merely bind the patient to granting or communicating permission for medical care; rather, it is marked by the intersubjectivity of a dialogical and collaborative process that is context-bound and rationally limited. Examining consent as an expression of the patient's therapeutic self-determination in telemedicine therefore calls for moving beyond a purely outcome-oriented view that focuses solely on the final declaration of will.

Since consent is not formed under ideal conditions of complete information, understanding, time, and subjective judgment, this work shifts the analytical focus toward the broader decision-making activity that structures and contextualizes therapeutic self-determination, namely metaconsent—the deliberation concerning the mode, dynamics, selection of variables and risks, their apprehension, and the trust placed in those responsible for conducting consent and shaping the underlying choice architecture

Telemedicine introduces distinctive technical, ethical, and legal features, particularly the often imagistic nature of diagnosis and dependence on visual and technological accuracy: loss of communicative quality, especially visual, can lead to significant diagnostic errors remediable through direct physical examination, while platform and device configuration may itself alter visual impressions, foster heuristics, and heighten bias risks, complicating even the documentation and archiving of image-based records and demanding special prudence in specifying agreements and privacy warnings.

The capacity of *privacy by design* to enhance metaconsent effectiveness in technology-mediated medical services depends on articulating and integrating legal, technical, and cognitive dimensions in optimizing how patient choices are formed and externalized. When metaconsent is shaped by proactive stances and by telemedicine systems that, from their inception, employ visual-design resources to highlight information relevant to the choice architecture, it can draw on *privacy by design* to sustain a reflective and continuous—but never fully rationally apprehensible—process that engages with the purportedly transparent, secure, and monitorable circumstances under which consent is produced and implemented.

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