Regulating the use of artificial intelligence in the doctor-patient relationship? A primer on supranational and national legal frameworks

Marta Fasan*

ABSTRACT: The paper aims at giving a general overview on the current regulatory frameworks concerning the use of AI systems within the doctor-patient relationship, assessing their effectiveness in minimising opacity and automation bias risks. The first section will focus on the supranational regulatory approach promoted by the Regulation (EU) n° 2024/1689 and will examine its applicative scope in the field of care relationship. The second part will analyse the regulatory solutions adopted at the national level, comparing the French and Italian normative approaches and the specific provision adopted to define doctors' duties and patients' rights. Finally, the paper will discuss the integration of various regulatory levels examined to establish a comprehensive regulatory framework for the use of AI in the doctor-patient relationship.

KEYWORDS: Artificial intelligence; doctor-patient relationship; European Union; France; Italy

SUMMARY: 1. Artificial intelligence in the doctor-patient relationship. Looking for legal solutions to emerging protection needs – 2. Regulating AI in care relationship. The AI Act and the EU's supranational approach – 3. Regulating AI in the care relationship. A comparative analysis of France and Italy's national approaches – 4. The multilevel and multisource regulation of AI in the doctor-patient relationship. A path to promote potentialities and fill in the gaps.

1. Artificial intelligence in the doctor-patient relationship. Looking for legal solutions to emerging protection needs

The development and widespread deployment of artificial intelligence (AI) systems are impressive challenges for contemporary legal frameworks. The capabilities of data analysis and inference offered by this technology present a scenario of undeniable complexity.[1] On the one hand, AI has been demonstrated to improve decision-making efficiency in a wide range of domains, being a

* *Research Fellow in Comparative Public Law, University of Trento. Mail: marta.fasan@unitn.it.* *This publication is financially supported by the European Union – Next Generation EU, Mission 4, Component 1, within the PRIN 2022 project "MEDICINE+AI, Law and Ethics for an Augmented and Human-Centered Medicine" (2022YB89EH) – CUP E53D23007020006. The article was subject to a double-blind peer review process.*

[1] Generally, on the technological competencies offered by AI systems see S. RUSSELL, P. NORVIG, *Artificial Intelligence: A Modern Approach*, London, 2020.

Call

valuable resource for both individuals and society at large.[2] Actually, the use of AI systems can enhance the promotion of people's interests and, in several circumstances, their compliance with the prevailing legal framework, resulting in a favourable influence on their legal status.[3] On the other hand, the implementation of AI leads to a new form of power which manifests the strength of private entities and companies involved in its development and production, as well as of AI operational mechanisms themselves. This emerging power is showing the potential to significantly impact societal structures, often in negative ways, with particularly critical consequences when it comes to promoting and protecting fundamental rights.[4]

As a result, contemporary legal systems need to provide legal tools and solutions aimed at limiting this pervasive technological power when it threatens to undermine the protection of individual rights. However, this should be done without completely compromising AI benefits.[5]

The outlined scenario and the related calls for protection are concretely illustrated by the implications of using AI systems within the context of the care relationship. While it is true that intelligent systems can facilitate the development of a therapeutic model focused on personalized care and patient well-being (thus completing the paradigm shift that has long influenced the legal framework of the care

[2] D. Kahneman, O. Sibony, C.R. Sunstein, *Noise. A Flaw in Human Judgment*, New York, 2021. The authors highlight the fundamental role AI technologies may have in removing all those kinds of "noise" that interferes in people's decision-making processes. More precisely, the term "noise" refers to all that unwanted variability affecting human judgments supposed to be identical and making them differ in the final decision. Thus, the "noise" presence creates unfair decisions and errors, which could have on people's lives.

[3] K. Yeung, *Why Worry about Decision-Making by Machine?*, in K. Yeung, M. Lodge (eds.), *Algorithmic Regulation*, Oxford, 2019, 34 ff. Thus, for example, in Belgium AI systems are being applied to personalize both labour supply and demand, improving the effectiveness of the implementation of active labour market policies. On this topic see S. Desiere, L. Struyven, *Using Artificial Intelligence to classify Jobseekers: The Accuracy-Equity Trade-off*, in *Journal of Social Policy*, 2, 2021, 367-385. Another example demonstrating AI capacity to enhance the compliance with the prevailing legal framework is given by the application of AI-driven models in tax administration. Cf. J.K. Nembe et al., *The Role of Artificial Intelligence in Enhancing Tax Compliance and Financial Regulation* , in *Finance & Accounting Research Journal*, 2, 2024, 241 ff.

[4] This pivotal topic has been analysed in C. O'Neil, *Weapons of Math Destruction. How Big Data Increases Inequality and Threatens Democracy*, New York, 2016; K. Crawford, *Atlas of AI. Power, politics, and Planetary Costs of Artificial Intelligence*, New Haven, 2021; S. Zuboff, *The Age of Surveillance Capitalism. The Fight for a Human Future at the New Frontier of Power*, London, 2018; J. Danaher, *The Threat of Algocracy: Reality, Resistance and Accommodation*, in *Philosophy & Technology*, 29, 2016, 245-268; E. Longo, *The Risks of Social Media Platforms for Democracy: A Call for a New Regulation*, in B. Curts, E. Fosch-Villaronga (eds.), *Law and Artificial Intelligence. Regulating AI and Applying AI in Legal Practice*, Berlin, 2022, 169 ff.; O. Pollicino, G. De Gregorio, *Constitutional Law in the Algorithmic Society*, in H.-W. Micklitz et al. (eds.), *Constitutional Challenges in the Algorithmic Society*, Cambridge, 2022, 5 ff. Among Italian legal scholars facing this issue see M.R. Ferrarese, *Poteri nuovi. Privati, penetranti, opachi*, Bologna, 2022; F. Parruzzo, *I sovrani della rete. Piattaforme digitali e limiti costituzionali al potere privato*, Napoli, 2022.

[5] Some legal scholars argue that this scenario give rise to a new form of constitutionalism, termed "digital constitutionalism", which aims at transposing the main values of contemporary constitutionalism in the light of the characteristics of the algorithmic and digital society. Cf. E. Celeste, *Digital Constitutionalism. The Role of Internet Bills of Right*, London, 2022, 76 ff.; G. De Gregorio, *Digital Constitutionalism in Europe. Reframing Rights and Powers in the Algorithmic Society*, Cambridge, 2022, 3 ff.; F. De Abreu Duarte, G. De Gregorio, A.J. Golia, *Perspective on digital constitutionalism*, in B. Brozek, O. Kanevskaia, P. Palka (eds.), *Research Handbook on Law and Technology*, Cheltenham-Northampton (MA), 2024, 315-329. For a critique of this theorisation see P. Terzis, *Against digital constitutionalism*, in *European Law Open*, 3, 2024, 336-352.

relationship),[6] the application of AI could introduce the risk of establishing a new and additional decision-making centre within the therapeutic process. Two factors are particularly significant to this end. The first one is the inner opacity of the most advanced AI systems. Such technology, despite its ability to produce highly accurate results, often lacks explainability. This is due to the complexities surrounding data analysis, classification, and interpretation within AI systems, which pose challenges even for technicians, coders, and designers.[7] This lack of transparency in the AI decision-making process can create significant barriers to fully understanding the reasoning and logical steps that intelligent systems take to arrive at specific conclusions. This issue, commonly referred to as the "black-box problem",[8] has the potential to negatively impact the relationship between doctors and patients. On one hand, healthcare professionals cannot effectively validate or deny the clinical hypotheses or treatment recommendations generated by AI, which undermines the trustworthiness of these tools[9] and raises important concerns regarding medical liability.[10] On the other hand, patients may lose faith in their doctors, who need to interpret and explain AI-generated choices while ensuring the adequacy and quality of health services. This lack of trust due to doctors' inability to provide complete information and explanation about AI diagnostic procedures could be a particularly crucial challenge when considering the importance of informed consent and trust within the legal context of the doctor-patient relationship.[11] Some legal scholars have stressed how the doctors' deficit of knowledge concerning AI

[6] This goal has been affirmed by the Council of Europe in the Recommendation 2185 (2020). Artificial Intelligence in Health Care: Medical, Legal and Ethical Challenges Ahead, 22 October 2020. Cf. E.J. TOPOL, *High-performance medicine: the convergence of human and artificial intelligence*, in *Nature Medicine*, 25, 2019, 44-56.

[7] These aspects are analyzed in M. EBERS, *Regulating AI and Robotics: Ethical and Legal Challenges*, in M. EBERS, S. NAVAS (eds.), *Algorithms and Law*, Cambridge, 2020, 48. The author highlights that technicians, coders, and designers may not even know the input data employed by AI or may only know them partially. On this topic, see Y. BATHAEE, *The Artificial Intelligence Black Box and the Failure of Intent and Causation*, in *Harvard Journal of Law & Technology*, 2, 2018, 901 ff.

[8] One of the first works using the term "black-box" is F. PASQUALE, *The Black Box Society. The Secret Algorithms That Control Money and Information*, Cambridge (MA)-London, 2015, 3 ff.

[9] See D. SCHÖNBERGER, *Artificial Intelligence in healthcare: a critical analysis of the legal and ethical implications*, in *International Journal of Law and Information Technology*, 27, 2019, 171-203; S. REDDY, *Explainability and artificial intelligence in medicine*, in *The Lancet Digital Health*, 4, 2022, e214-e215; C. WOODCOCK ET AL., *The Impact of Explanations on Layperson Trust in Artificial Intelligence-Driven Symptom Checker Apps: Experimental Study*, in *Journal of Medical Internet Research*, 11, 2021, 1-20. A different view is offered in A.J. LONDON, *Artificial Intelligence and Black-Box Medical Decisions: Accuracy versus Explainability*, in *Hastings Center Report*, 1, 2019, 16 ff. The author highlights that human doctors don't explain their decision-making process, or the logical steps followed in this procedure to their patients. A critical overview of the current explainability methods is also offered in M. GHASSEMI, L. OAKDEN-RAYNER, A.L. BEAM, *The false hope of current approaches to explainable artificial intelligence in health care*, in *The Lancet Digital Health*, 3, 2021, e743-e750.

[10] On the liability issues due to AI application cf. F. MOLNÁR-GÁBOR, *Artificial Intelligence in Healthcare: Doctors, Patients and Liabilities*, in T. WISCHMEYER, T. RADEMACHER (eds.), *Regulating Artificial Intelligence*, Cham, 2020, 348 ff.; X. LIU ET AL., *The medical algorithmic audit*, in *The Lancet Digital Health*, 5, 2022, e384-e397; M.M. MELLO, N. GUHA, *Understanding Liability Risk from Using Health Care Artificial Intelligence Tools*, in *The New England Journal of Medicine*, 3, 2024, 271-278.

[11] See B. MITTELSTADT, The *doctor will not see you. The algorithmic displacement of virtuous medicine*, in P. OTTO, E. GRÄF (eds.), *3TH1CS. A reinvention of ethics in the digital age?*, Berlin, 2017, 68-77; C. CASONATO, *AI and Constitutionalism: The Challenges Ahead*, in B. BRAUNSCHWEIG, M. GHALLAB (eds.), *Reflections on Artificial Intelligence for Humanity*, Cham, 2021, 127-149.

decision-making logic may impact the quality of the informed consent process, which is aimed at ensuring patients' right to therapeutic self-determination.[12] Without knowing the rationale behind AI outputs and recommendations or even the presence of AI support in medical decision-making,[13] patients may not be able to fully understand their medical condition and to express their relevant personal values, posing a threat to patients' autonomy and right to make informed decisions.[14]

The second relevant factor, then, is the phenomenon known as "automation bias". This term identifies the situation when the doctor over-relies on AI results, overlooking errors and biases "that should have been spotted by human-guided decision-making".[15] Indeed, even without a full delegation of clinical judgment, an excessive trust on AI functions, with an uncritical deference to its outputs, may lead doctors to ignore their scientific expertise and just rubber-stamp the AI recommendation.[16] This kind of "oracular" approach to AI can also have negative consequences on the doctor-patient relationship.[17]

On doctors' side, such a growing use of AI in healthcare could lead to the deskilling of healthcare professionals. The described dependency on AI solutions can diminish their skills and expertise over time, like for example their diagnostic ability and awareness, making it harder for healthcare professionals to recognize and detect the symptoms of specific diseases.[18] Moreover, the effects of this potential deskilling are particularly pronounced for medical skills that go beyond strictly scientific knowledge. The phenomenon of "automation bias" AI systems may bring doctors to disregard essential human

[12] D. Schiff, J. Borenstein, *How Should Clinicians Communicate With Patient About the Roles of Artificially Intelligent Team Members?*, in *AMA Journal of Ethics*, 2, 2019, 138-145; M. Daverio, *Informed Consent and Medicial Decision-Making Applying Artificial Intelligence. Ethical Aspects and Implications for the Doctor-Patient Relationship*, in *Rivista di filosofia del diritto*, 2, 2023, 419-438; K. Astromské, E. Peičius, P. Astromskis, *Ethical and legal challenges of informed consent applying artificial intelligence in medical diagnostic consultations*, in *AI & Society*, 36, 2021, 509-520;

[13] It should be emphasised that not all legal scholars agree on the existence of these information requirements. For example, in I. Glenn Cohen, *Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?*, in *The Georgetown Law Journal*, 108, 2020, 1425-1469, the author argues that, according to the informed consent legal doctrine in the United States, the failure to inform patients of AI application will not violate the law of the informed consent. This assumption is based on comparing AI systems and other inputs of medical decision-making (training, education, journal articles, etc.). In these terms, doctors have no duty to disclose these different elements, similarly, they don't have to inform patients about AI's presence in their medical decision-making process. This thesis is also supported in C. De Menech, *Intelligenza artificiale e autodeterminazione in materia sanitaria*, in *BioLaw Journal – Rivista di BioDiritto*, 1, 2022, 181-203.

[14] V.L. Raposo, *The fifty shades of black: about balck box AI and explainability in healthcare*, in *Medical Law Review*, 33, 2025, 1-22; M. Kiener, *Artificial intelligence in medicine and the disclosure of risks*, in *AI & Society*, 36, 2021, 705-713.

[15] World Health Organization (WHO), *Ethics and Governance of Artificial Intelligence for Health. WHO guidance*, Geneva, 2021, 45, at https://www.who.int/publications/i/item/9789240029200 (last accessed 03/03/2025).

[16] M. Daverio, *op. cit.*, 427 ff.; World Health Organization (WHO), *op. cit.*, 45 ff.; R. Khera, M.A. Simon, J.S. Ross, *Automation Bias and Assistive AI. Risk of Harm From AI Driven Clinical Decision Support*, in *JAMA*, 23, 2023, 2255-2257; A. Simoncini, E. Longo, *Fundamental Rights and the Rule of Law in the Algorithmic Society*, in H.-W. Micklitz et al. (eds.), *Constitutional Challenges in the Algorithmics Society*, Cambridge, 2022, 39 ff.

[17] F. Cabitza, R. Rasolini, G. Genesini, *Unintended Consequences of Machine Learning in Medicine*, in *JAMA*, 6, 2017, 517.

[18] V. Buch, G. Varughese, M. Maruthappu, *Artificial intelligence in diabetes care*, in *Diabetic Medicine*, 4, 2018, 497; F. Cabitza, R. Rasolini, G. Genesini, *op. cit.*, 517 ff.

aspects and factors that are crucial for delivering effective and personalized care. The inability to incorporate these factors into AI decision-making could lead to mistakes or serious failures in clinical practice and can adversely impact doctors' self-confidence and willingness to diagnose without AI assistance.[19] The "automation bias" and the related deskilling effect also pose risks on the patients' side. The doctors' overreliance on AI results can undermine patients' confidence, especially when the effects of deskilling become evident within the therapeutic relationship.[20] Likewise, the potential inability of healthcare professionals to critically rely on the AI-generated results can negatively affect patients' health and safety. Neglecting to recognize the errors and biases in the decision-making processes used by AI, while wrongly assuming that technology is neutral and infallible,[21] can result in a decline in the quality of healthcare services provided to patients, ultimately putting their health at risk.[22]

The inability to discern the rationale behind an AI output, such as a diagnostic result, combined with the risk that healthcare professionals may over-rely on AI decisions are issues that, while problematic in themselves,[23] are both elements which can significantly change the ethical and legal core values of the therapeutic relationship, because they could shift decision-making authority from the therapeutic alliance involving doctors and patients to a predominantly technological sphere.

Such an outcome may undermine the current legal framework governing the care relationship, which, within the Western Legal Tradition, prioritizes the patient's autonomy and the dialogue between patient and physician to uphold the centrality of the individuals and their choices.[24] Without sufficient safeguards and measures to mitigate the deterministic effects of AI, incorporating this technology into

[19] T. Hoff, *Deskilling and adaptation among primary care physicians using two work innovations*, in *Health Care Management Review*, 4, 2011, 338-348; J. Chen et al., *Potential Trade-Offs and Unintended Consequences of AI*, in M. Matheny et al. (eds.), *Artificial Intelligence in Health Care: the Hope, the Hype, the Promise, the Peril*, Washington, 2019, 103 ff.

[20] M. Daverio, *op. cit.*, 427 ff.; K. Astromské, E. Peičius, P. Astromskis, *op. cit.*, 509-520; B. de Boer, O. Kudina, *What is morally at stake when using algorithms to male medical diagnoses? Expanding the discussion beyond risks and harms*, in *Theoretical Medicine and Bioethics*, 42, 2021, 245-266; E.-H.W. Kluge, *Artificial intelligence in healthcare: Ethical considerations*, in *Healthcare Management Forum*, 1, 2020, 47-49.

[21] R. Sparrow, J. Hatherley, *High Hopes for "Deep Medicine"? AI, Economics, and the Future of Care*, in *Hastings Center Report*, 1, 2020, 14 ff.

[22] B. Mittelstadt (Steering Committee For Human Rights In The Fields Of Biomedicine And Health, Council of Europe), *The impact of artificial intelligence on the doctor-patient relationship*, Strasbourg, 2021, 53 ff.

[23] The described elements are not the only problematic ones that can arise from the use of AI in the medical field. For example, risks concerning the doctor substitution, the impoverishment of a holistic approach to health, the protection of people's right to privacy and the liability allocation may arise when implementing AI in this context. On these topics see M. Daverio, *op. cit.*, 419 ff.; V.L. Raposo, *op. cit.*, 1 ff.; B. Mittelstadt (Steering Committee For Human Rights In The Fields Of Biomedicine And Health, Council of Europe), *op. cit.*, 4-67.

[24] Concerning the legal recognition of the patient-centred model cf. J.G. Culhane et al., *Toward a Mature Doctrine of Informed Consent: Lessons From a Comparative Law Analysis*, in *British Journal of American Legal Studies*, 1, 2012, 558-560; R. Porcher, *Le consentement en droit médical*, in *Médicine & Droit*, 154, 2019, 8-19; J. Cantero Martínez, *La configuración legal y jurisprudencial del derecho constitucional a la proteccion de la salud*, in *Revista Vasca de Administración Pública*, 80, 2008, 40 ff.; C. Casonato, *La miglior legge oggi possibile*, in *The Future of Science and Ethics*, 2, 2017, 106 ff.

the care relationship could lead to a new form of technological paternalism. And this, in turn, may jeopardise the rights and protections that currently uphold the doctor-patient relationship.[25]

Given this scenario and the need to prevent AI from lowering the existing safeguards in this field, this paper aims at analysing the potential effectiveness of the current regulatory frameworks and the eventual presence of loopholes concerning the use of AI systems within the doctor-patient relationship. More precisely, the paper will examine the role of hard law tools that regulate the use of AI within the European territory, even though the existence of several soft law documents on this subject.[26] For these reasons, the first section will focus on the supranational regulatory approach promoted by the Regulation (EU) n° 2024/1689 and will examine its applicative scope in the field of care relationship. The second part will analyse the regulatory solutions adopted at the national level, comparing the French and Italian normative approaches and the specific provision adopted to define doctors' duties and patients' rights. Indeed, these two legal systems serve as paradigmatic case studies for understanding the guarantees to be implemented, specifically regarding the use of AI in the therapeutic relationship, and their potential integration with the supranational regulatory framework.[27] Finally, the paper will discuss integrating the examined regulatory levels to establish a comprehensive legal framework for using AI in the doctor-patient relationship. These final considerations will also allow for reflections on potential regulatory gaps and the need for additional regulatory sources to address this area

[25] B. MITTELSTADT (Steering Committee For Human Rights In The Fields Of Biomedicine And Health, Council of Europe), *op. cit*., 44 ff.

[26] The reference pertains to documents drawn up internationally by the World Health Organization (WHO), which outline a set of ethical and legal principles and recommendations regarding the AI implementation in healthcare relationship. See World Health Organization (WHO), *Ethics and governance of artificial intelligence for health. Guidance on large multi-modal models*, Geneva, 2024, 1-77, at https://www.who.int/publications/i/item/9789240084759 (last accessed 03/03/2025); World Health Organization (WHO), *Ethics and Governance of Artificial Intelligence for Health. WHO guidance*, cit., 1 ff.

[27] On the importance of case selection, according to different methodological criteria, in comparative public law analyses see R. HIRSCHL, *The Questions of Case Selection in Comparative Constitutional Law*, in *The American Journal of Comparative Law*, 1, 2005, 125-155. Legal comparison plays a fundamental role in analysing the challenges AI pose to traditional legal categories and in identifying potential regulatory solutions, as stated by many legal scholars. Cf. G. GUERRA, *An Interdisciplinary Approach for Comparative Lawyers: Insights from the Fast-Moving Field of Law and Technology*, in *German Law Journal*, 3, 2018, 579-612. Among italian legal scholars cf. A. VEDASCHI, *Tecnologia,* counter-terrrorism *e diritti*, in *Diritto pubblico comparato ed europeo*, Numero speciale, 2024, 979 ff.; G. SMORTO, *Il ruolo della comparazione giuridica nella contesa per la sovranità digitale*, in *DPCE online*, 1, 2023, 339 ff.; R. SCARCIGLIA, *Scienza della complessità e comparazione giuridica nell'età dell'asimmetria*, in *Diritto pubblico comparato ed europeo*, Numero speciale, 2019, 703 ff.; G. RESTA, *L'albero e l'onda: il discorso della comparazione al crocevia tra le discipline*, in G. RESTA, A. SOMMA, V. ZENO-ZENCOVICH (eds.), *Comparare. Una riflessione tra le discipline*, Milano-Udine, 2020, 9-37; G. GUERRA, *La complessità e lo strumentario del comparatista. Alcuni esempi dal diritto delle tecnologie*, in *Diritto pubblico comparato ed europeo*, 4, 2020, 831-868; S. PENASA, *Diritto e tecnologia nella recente riflessione giuridica comparata: "etichette" concettuali, sistemi di produzione normativa e metodi della comparazione*, in *Diritto pubblico comparato ed europeo*, Numero speciale, 2024, 973.

2. Regulating AI in care relationship. The AI Act and the EU's supranational approach

The need to regulate the development and use of artificial intelligence (AI), especially in its most sensitive applications, has become a key priority for the European Union in recent years. This focus has led to the adoption of Regulation (EU) 2024/1689, commonly known as the Artificial Intelligence Regulation or AI Act.[28] The primary goal of this act is to establish a uniform regulatory framework across Europe Union concerning the production and deployment of AI systems, thereby ensuring their circulation and commercialization within the EU single market in full alignment with the core values of the Union.[29]

The Artificial Intelligence Regulation adopts a regulatory approach characterized by three key elements. First, it introduces a horizontal framework, meaning that the obligations and requirements apply to AI systems in general, without specific differentiation based on specific fields of application or their unique characteristics.[30] Second, the AI Act employs a risk-based approach, imposing increasingly stringent requirements as the potential risks to health, safety, and fundamental rights increase[31]. Third, the Regulation aligns with the New Legislative Framework, the EU's regulatory model that includes specific mechanisms for market surveillance both before and after a product is put into the market to ensure consumer protection.[32]

Although the Regulation (EU) 2024/1689 is not exclusively focused on the use of AI within therapeutic relationships, its overarching framework contains provisions that can be applied to this context, albeit with some gaps in content specificity. In this light, the following discussion aims at identifying which

[28] Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 200/2008, (EU) No 167/2013, (EU) No 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act). The Regulation formally entered into force on 1 August 2024, but its practical implementation will be subject to a variable schedule, depending on the specifics of its chapters, as stated by art. 113. It should be emphasized that the European Union's intention to regulate AI technologies has also been achieved through the adoption of other regulatory acts that complement the legal framework provided by the AI Act. In this perspective, the GDPR, the Data Act, the Data Governance Act, the Digital Service Act, the Digital Markets Act, the Cybersecurity Act and the recent Regulation on the European Health Data Space must therefore be considered relevant in the regulation of AI. See G. FINOCCHIARO, *The regulation of artificial intelligence*, in *AI & Society*, 39, 2024, 1961-1968, and among Italian legal scholars O. POLLICINO, *Regolare l'intelligenza artificiale: la lunga via dei diritti fondamentali*, in O. POLLICINO ET AL. (eds.), *La disciplina dell'intelligenza artificiale*, Milan, 2025, 3-39.

[29] V.L. RAPOSO, *Ex machina: preliminary critical assessment of the European Draft Act on artificial intelligence*, in *International Journal of Law and Information Technology*, 30, 2022, 88 ff. The goals pursued are explicitly affirmed by art. 1(1), Regulation (EU) 2024/1689.

[30] Art. 1(2), Regulation (EU) 2024/1689. See also M. VEALE, F. ZUIDERVEEN BORGESIUS, *Demystifying the Draft EU Artificial Intelligence Act*, in *Computer Law Review International*, 4, 2021, 98.

[31] P. DUNN, G. DE GREGORIO, *The Ambiguous Risk-Based Approach of the Artificial Intelligence Act: Links and Discrepancies with Other Union Strategies*, in D. DUSHI ET AL. (eds.), *Proceedings of the Workshop on Imaging the AI Landscape after the AI Act (IAIL 2022)*, Amsterdam, 2022, 1-9; J. SCHUETT, *Risk Management in the Artificial Intelligence Act*, in *European Journal of Risk Regulation*, 2023, 1-19; M. EBERS, *Truly Risk-based Regulation of Artificial Intelligence. How to Implement the EU's AI Act*, in *European Journal of Risk Regulation*, 6 November 2024, 1-20.

[32] M. EBERS, *Standardizing AI. The Case of the European Commission's Proposal for an "Artificial Intelligence Act"*, in L.A. DIMATTEO, C. PONCIRÒ, M. CANNARSA (eds.), *The Cambridge Handbook of Artificial Intelligence. Global Perspectives on Law and Ethics*, Cambridge, 2022, 321-344.

guarantees outlined in the AI Act can be implemented in the context of AI use in therapeutic relationships, considering the problematic issues of AI opacity and automation bias and examining which role the main characters of the doctor-patient relationship have under the obligations provided by the EU Regulation.

Firstly, it is important to highlight how the application of AI in this domain falls within the framework established by the AI Act, as delineated by the combined provisions of Article 6(1)(a) of Regulation 2024/1689 and Article 2(1) of Regulation 2017/745 (also known as Medical Devices Regulation, MDR). These provisions allow for the interpretation that any medical device, as defined by the Regulation encompassing "any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for […] diagnosis, prevention, monitoring, prediction, prognosis, treatment, or mitigation of disease, […] or compensation for an injury or disability",[33] whose safety component is an AI system, or which itself is an AI system, is classified as a high-risk system under the AI Act.[34] In addition to this, Article 6(2) of the AI Act categorizes AI technologies used by or on behalf of public authorities to assess individuals' eligibility for healthcare services and those employed for triage procedures as high-risk AI systems.[35] The described classification entails that the requirements and obligations imposed on providers and deployers of high-risk AI systems, which represent most of the provisions contained in the AI Act, are applicable to AI systems used in the context of therapeutic relationships.

Taking into consideration the main aim of this paper, the analysis of the provisions concerning providers will not be addressed here,[36] as will be the integration and coordination between AI Act provisions

[33] Art. 2(1), Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. It is important to note that the analysis of different types of AI-based medical devices and their specific functions is out of the scope of this paper. Instead, the focus is on their capacity to assist in developing diagnoses, prognoses, and treatments, and their potential role in the doctor-patient relationship.

[34] Art. 6(1), Regulation (EU) 2024/1689. This classification of AI-based medical devices as high-risk systems is due to the inclusion of the Medical Device Regulation within the EU harmonisation legislation listed in the Annex I of the AI Act. It is important to note that AI-based medical device classified as high-risk systems under art. 6(1) are not covered by art. 6(3) exception. This provision states that only AI systems referred to in Annex III can be exempted from the requirements for high-risk systems if they are: intended to perform a narrow procedural task; to improve the outcome of a previously performed human activity; to detect decision patterns or deviations from previous decisions patterns, and are not intended to replace or influence the previously performed human assessment without proper human review; or are intended to perform a preparatory task for an assessment relevant to the purpose of the use cases listed in Annex III. See F. BUSCH ET AL., *Navigating the European Union Artificial Intelligence Act for Healthcare*, in *NPJ Digital Medicine*, 7, 2024, 1-6.

[35] This is affirmed by the combined provision of art. 6(2) and Annex III, No. 5(a) and (d), Regulation (EU) 2024/1689.

[36] Taken into account who is considered provider under art. 3(1), No 3, Regulation (EU) 2024/1689 (""provider" means a natural or legal person, public authority, agency or other body that develops an AI system or a general-purpose AI model or that has an AI system or a general-purpose AI model developed and places it on the market or puts the AI system into service under its own name or trademark, whether for payment or free of charge"), it seems evident that neither doctors, healthcare professionals or patients could covered by this definition. Thus, the provider's obligations established by the AI Act are not relevant in the context of the doctor-patient relationship.

ISSN 2284-4503

and the legal framework provided by other applicable medical legislations.[37] Therefore, the essay will focus more on the obligations of deployers under AI Act and on all the other relevant provisions that could be applied to the doctor-patient relationship. According to Article 3(4) of Regulation (EU) 2024/1689, deployers may include doctors and healthcare professionals who use AI systems under their professional authority and, for this reason, have the possibility to attempt to mitigate the negative effects due to opacity and automation bias.[38] In this regard, certain provisions of the AI Act, outlining the obligations of deployers of high-risk AI systems, are particularly relevant.

More precisely, provisions requiring deployers to monitor the AI system's operation in accordance with its instructions for use and to ensure that the input data under their control are relevant and sufficiently representative for the system's intended purpose are both applicable to doctors and healthcare professionals when using AI in the context of the care relationship.[39] Furthermore, if a risk to health, safety, or fundamental rights arises, or a serious incident occurs during the use of the AI system in accordance with the given instructions, Article 26 states the deployer must inform the provider, the distributor, and the relevant market surveillance authority, following the procedures outlined in the Regulation.[40] Additionally, Article 26 requires deployers of high-risk AI systems, that make or assist in decisions affecting natural persons, to inform those people that they are subject to the use of a high-risk AI system, a provision that is equally relevant in the care context.[41]

In addition to these obligations, Regulation (EU) 2024/1689 establishes further provisions that involve deployers and may hold significant regulatory implications for the use of AI within the doctor-patient relationship. In outlining the requirements that high-risk AI systems must fulfil to obtain the CE mark and be placed on the EU market, the AI Act requires that deployers receive adequate training to ensure the effective implementation of measures aimed at managing and mitigating the risks associated with AI systems. This training should consider the deployer's technical knowledge, education, experience,

[37] This is the reason why the present paper will not examine the complex relationship between AI Act provisions and Medical Device Regulation ones. Moreover, the Medical Device Regulation is a product-based regulation, focusing on providing obligations to ensure the production of safe and secure medical devices and not on the obligation of whose should use the product in their professional activities. Nevertheless, the integration and coordination between the AI Act and the Medical Device Regulation will be one of the most important legal issues to address the application of AI to the medical field in the next future. This entails that both Artificial Intelligence Regulation and Medical Device Regulation apply to this kind of systems, with the need to define a complementarity between the two Regulations and their applicable rules and obligations. On this topic cf. F. GENNARI, *O Complementarity, Where Art Thou? Wading through the Medical Device Regulation and the AI Act Compliance: The case of Software as a Medical Device. A Primer*, in *BioLaw Journal – Rivista di BioDiritto*, 3, 2024, 411-453.

[38] B. SOLAIMAN, A. MALIK, *Regulating algorithmic care in the European Union: evolving doctor-patient models through the Artificial Intelligence Act (AI – Act) and the liability directives*, in *Medical Law Review*, 1, 2025, 13 ff.

[39] Art. 26(1) and (4), Regulation (EU) 2024/1689.

[40] Art. 26(5), Regulation (EU) 2024/1689. This specific provision becomes an even more important guarantee for the protection of people within the therapeutic relationship. Doctors and healthcare professionals are the only parties able to monitor and report the occurrence of such situations, demonstrating the importance of maintaining their supervision during the application of AI. Generally, on this topic cf. M. VERDICCHIO, A. PERIN, *When Doctors and AI interact: on Human Responsibility for Artificial Risks*, in *Philosophy & Technology*, 11, 2022, 1-28.

[41] Art. 26(11), Regulation (EU) 2024/1689.

and expected competence, as well as the potential contexts in which the intelligent system will be used.[42]

Additionally, the Regulation emphasizes the necessity of ensuring a level of transparency that allows deployers to accurately interpret the system's outputs and appropriately apply them.[43] Deployers must receive clear, comprehensible, relevant, and accessible instructions for use, which should include the information needed to interpret the system's output and the human oversight measures that facilitate understanding its operation and outcomes.[44]

Regarding human oversight, the AI Act lays down that people, whom human oversight measures are assigned, must be capable of understanding the system's capabilities and limitations.[45] They are required to monitor the system's performance, document any unexpected anomalies or malfunctions, be aware of the risk of over-reliance on the AI's output, and accurately interpret the results.[46] Furthermore, they must be able to intervene in or stop the system's operation and, if necessary, decide to disregard or override the AI-generated output.[47] This oversight must be conducted with due regard to the transparency requirements outlined in Article 13, ensuring that the deployer can make informed decisions about the system's use.[48]

The outlined regulatory framework provides some safeguards that doctors and healthcare professionals can implement when integrating AI into the therapeutic relationship. Specifically, concerning the risks associated with opacity and automation bias, the Regulation states that these risks can be mitigated or controlled through measures that ensure doctors and healthcare professionals have sufficient information to interpret AI-generated results. This enables them to use the outputs appropriately within their professional practice, recognizing the system's limitations, and remaining aware of the potential for over-reliance on AI outputs. Consequently, healthcare providers can retain the discretion

[42] Art. 9(5), Regulation (EU) 2024/1689.

[43] Art. 13(1), Regulation (EU) 2024/1689.

[44] These obligations and requirements are provided by art. 13(2) and (3), letters b(vii) and c, Regulation (EU) 2024/1689.

[45] Art. 14(4), letter a, Regulation (EU) 2024/1689.

[46] Art. 14(4), letters b and c, Regulation (EU) 2024/1689. The first mentioned provision is the main explicit guarantee to avoid the risk of automation bias. It entails that human oversight measures and requirements are the main tools offered to protect people's rights, also within the therapeutic context, when facing this specific risk. Generally, cf. L. ENQVIST, *'Human oversight' in the EU artificial intelligence act: what, when and by whom?*, in *Law, Innovation and Technology*, 2, 2023, 508-535; J. LAUX, *Institutionalised distrust and human oversight of artificial intelligence: towards a democratic design of AI governance under the European Union AI Act*, in *AI & Society*, 39, 2024, 2853-2866. Concerning the human oversight measures within the medical field P. HASELAGER ET AL., *Reflections Machines: Supporting Effective Human Oversight Over Medical Decision Support Systems*, in *Cambridge Quarterly of Healthcare Ethics*, 3, 2024, 380-389.

[47] Art. 14(4), letters d and c, Regulation (EU) 2024/1689. In C. CASONATO, *Unlocking the Synergy: Artificial Intelligence and (old and new) Human Rights*, in *BioLaw Journal – Rivista di BioDiritto*, 3, 2023, 233-240, the author identifies human oversight measures as the expression of a new human right, the right to the hero. In these terms, such a new right should require a professional who not only has a specific technological expertise but also is sufficiently brave to disregard AI outputs, assuming the responsibility and all the corresponding risks of a similar choice.

[48] The need to understand AI functioning and limits to properly exercise the human oversight is outlined in A. HOLZINGER, K. ZATLOUKAL, H. MÜLLER, *Is human oversight to AI systems still possible?*, in *New Biotechnology*, 85, 2025, 59-62.

to opt-out using AI in their professional activities if necessary.[49] Moreover, these transparency and human oversight requirements can play a fundamental role in ensuring both the protection and effectiveness of the right to informed consent. By understanding the decision-making process of an AI system, physicians can effectively explain the outcomes to patients, providing them with all the necessary information to make an informed and autonomous decision.[50] However, despite the existence of these requirements and obligations, they may not be sufficient to minimise the risks arising from the use of IA and to protect the rights recognised in the doctor-patient relationship. Such obligations of transparency and human oversight should be supported by the adoption of both technological and educational measures aimed at explaining AI functioning and improving doctors' literacy on AI.[51] Only in this way, it will be possible to give doctors and healthcare professionals proper and effective tools to minimise, for example, mistakes and biases that could occur in the AI decision-making process.[52]

Regarding the other key participant in the care relationship—the patient—the AI Act introduces relatively few provisions that directly apply.[53] One notable requirement is the transparency obligation under Article 50, which requires that individuals interacting with AI systems – such as chatbots providing medical advice or conducting health monitoring[54] – must be informed that they are engaging with an

[49] The importance of transparency and human oversight requirements to make healthcare professionals able to control AI functioning and operations is described also in B. Solaiman, A. Malik, *op. cit.*, 14 ff.

[50] F. Molnár-Gábor, *op. cit.*, 346 ff.; B. Mittelstadt, *The doctor will not see you now. The algorithmic displacement of virtuous medicine*, cit., 68-77; D. Schiff, J. Borenstein, *op. cit.*, 138-145. Among Italian legal scholars cf. C. Casonato, *Costituzione e intelligenza artificiale: un'agenda per il prossimo futuro*, in *BioLaw Journal – Rivista di BioDiritto*, Special Issue 2, 2019, 718 ff.; L. Scaffardi, *La medicina alla prova dell'Intelligenza Artificiale*, in *DPCE online*, 1, 2022, 349-359.

[51] In these terms, the implementation of solutions by design and of specific training programmes will be a fundamental step to ensure the compliance with AI Act requirements and obligations. On the application of technical and by design measures see L. Lessig, *Code and Other Laws of Cyberspace*, New York, 1999; R. Brownsword, *Law 3.0*, Abingdon-New York, 2020, 28; G. Mobilio, *L'intelligenza artificiale e i rischi di una "*disruption*" della regolamentazione giuridica*, in *BioLaw Journal – Rivista di BioDiritto*, 2, 2020, 415-418; K. Yeung, *Towards an Understanding of Regulation by Design*, in R. Brownsword, K. Yeung (a cura di), *Regulating Technologies. Legal Features, Regulatory Frames and Technological Fixes*, Oxford-Portland, 2008, 81 ff. On the role of AI literacy, it is important to note that article 4 of the Regulation (EU) 2024/1689 states "Providers and deployers of AI systems shall take measures to ensure, to their best extent, a sufficient level of AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used".

[52] E. Fosch-Villaronga, A. Poulsen, *Diversity and Inclusion in Artificial Intelligence*, in B. Custers, E. Fosch-Villaronga (eds.), *Law and Artificial Intelligence. Regulating AI and Applying AI in Legal Practice*, The Hague, 2022, 117 ff.; C. Nardocci, *Artificial Intelligence-based Discrimination: Theoretical and Normative Responses. Perspectives from Europe*, in *DPCE online*, 3, 2023, 2367-2393.

[53] The lack of provisions applicable to patients and, generally, concerning ordinary people is criticised in N. Smuha et al., *How the EU can achieve Legally Trustworthy AI: A Response to the European Commission's Proposal for an Artificial Intelligence Act*, 5 August 2021, https://strathprints.strath.ac.uk/85567/1/Smuha_etal_SSRN_2021_How_the_EU_can_achieve_legally_trustworthy_AI.pdf (last accessed 19/01/2025); L. Floridi, *The European Legislation on AI: a Brief Analysis of its Philosophical Approach*, in *Philosophy & Technology*, 2, 2021, 215-222.

[54] On this specific kind of AI applications see B. Mittelstadt et al., *The Ethical Implications of Personal Health Monitoring*, in *International Journal of Technoethics*, 2, 2014, 37-60; K. Denecke et al., *Artificial Intelligence for Participatory Health: Applications, Impact, and Future Implications*, in *Yearbook of Medical Informatics*, 1, 2019,

AI system[55]. Additionally, the related output should be recognisable as an AI-generated content[56]. Other than such a right to know the artificial nature of the system[57], the AI Act does not provide any other rights, obligations or duties for subjects such as patients[58]. This is true even regarding general-purpose AI systems, despite their growing significance in the medical field[59]. Not even the "right to an explanation", as outlined in the Regulation (EU) 2024/1689, does not appear to extend to patients. According to the text, this right is reserved for affected people subject to decisions taken on the basis of the output from a high-risk AI system listed in Annex III, which notably does not include medical devices[60].

165-173; S. COGHLAN ET AL., *To chat or bot to chat: Ethical issues with using chatbots in mental health*, in *Digital Health*, 9, 2023, 1-11. These AI systems could play a fundamental role in promoting the patients' information and awareness on their health conditions, enhancing their empowerment within the therapeutic relationship. Such aspect has been analysed among Italian legal scholars in C. CASONATO, S. PENASA, *Intelligenza artificiale e medicina del domani*, in G.F. FERRARI (ed.), *Le smart cities al tempo della resilienza*, Milano-Udine, 2021, 553-586; M. TOMASI, *Il volto umano della salute digitale nelle città intelligenti*, in *ivi*, 519-551 A. PALLADINO, M. FARINA, *Le politiche pubbliche nella società costituzionale* data driven. *Big Data e tutela "mobile" della salute tra poteri pubblici e privati*, in *Diritto pubblico comparato ed europeo*, 1, 2023, 117-142.

[55] Art. 50(1), Regulation (EU) 2024/1689. The provision states that the disclaimer concerning the artificial nature of the system is not required when this is an obvious information "[...] from the point of view of a natural person who is reasonably well-informed, observant and circumspect, taking into account the circumstances and the context of use".

[56] Art. 50(2), Regulation (EU) 2024/1689. See also F. BUSCH ET AL., *op. cit.*, 3; E. LONGO, F. PAOLUCCI, *The Article 50 of the AI Act and the Transparency Obligations: the Model and its Limitations*, in O. POLLICINO, F. DONATI, G. FINOCCHIARO, F. PAOLUCCI (eds.), *La disciplina dell'intelligenza artificiale*, Milano, 2025, 275 ff.

[57] In C. CASONATO, *Unlocking the Synergy: Artificial Intelligence and (old and new) Human Rights*, cit., 235 ff., the author theorises the existence of the described right as an expression of the informed consent.

[58] B. SOLAIMAN, A. MALIK, *op. cit.*, 16 ff.

[59] On the use of general-purpose AI systems, and more precisely ChatGPT, in the described field see T. HIROSAWA ET AL., *Diagnostic Accuracy of Differential-Diagnosis Lists Generated by Generative Pretrained Transformer 3 Chatbot for Clinical Vignettes with Common Chief Complaints: A Pilot Study*, in *International Journal of Environmental Research and Public Health*, 4, 2023, 1-10; J. LIU, C. WANG, S. LIU, *Utility of ChatGPT in Clinical Practice*, in *Journal of Medical Internet Research*, 25, 2023, 1-7. Considering the AI Act provisions on general-purpose AI models, it is important to note that they primarily focus on classifying these systems (whether systemic risk or not) and outlining the obligation of the providers, as stated by Articles 51, 52 and 53, Regulation (EU) 2024/1689.

[60] Art. 86, Regulation (EU) 2024/1689. The limited scope of the current drafting of the right to explanation is analysed in S. DEMKOVA, *The AI Act's Right to Explanation: A Plea for an Integrated Remedy*, 31 October 2024, in https://www.medialaws.eu/the-ai-acts-right-to-explanation-a-plea-for-an-integrated-remedy/ (last accessed 19/01/2025); G. PAVLIDIS, *Unlocking the black box: analysing the EU artificial intelligence act's framework for explainability in AI*, in *Law, Innovation and Technology*, 1, 2024, 293-308; F. PALMIOTTO, *The AI Act Roller Coaster: The Evolution of Fundamental Rights Protection in the Legislative Process and the Future of the Regulation*, in *European Journal of Risk Regulation*, 17 January 2025, 1-24. Generally, on the importance of this right cf. F. PALMIOTTO, *When Is a Decision Automated? A Taxonomy for a Fundamental Rights Analysis*, in *German Law Journal*, 2, 2024, 210-236. In S. DALTON-BROWN, *The Ethics of Medical AI and the Physician-Patient Relationship*, in *Cambridge Quarterly of Healthcare Ethics*, 29, 2020, 115-121, the author argues the existence of a right to explanation on decisions made by AI systems under art. 22, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation, also known as GDPR). The existence of a such a right to explanation within the GDPR has been criticised in S. WACHTER, B. MITTELSTADT, L. FLORIDI, *Why a Right to Explanation of Automated Decision-Making Does Not Exist in the General Data Protection Regulation*, in *International Data Privacy Law*, 2, 2017, 76-99.

The same considerations apply to the obligations outlined in Article 26(11) of the Regulation (EU) 2024/1689. Since this provision is limited to the high-risk systems specified in Annex III, it cannot be supposed that a doctor is required to inform patients about the use of AI in the diagnostic process that affects them. Consequently, the patient does not have the right to receive this information under the provisions of the AI Act.[61]

3. Regulating AI in the care relationship. A comparative analysis of France and Italy's national approaches

The European Union, as seen, has opted for a general and horizontal regulatory approach to artificial intelligence, thereby not accounting for the specific regulatory nuances that may distinguish each area of application. Conversely, the approach taken at the national level to regulate the use of AI in the doctor-patient relationship differs, reflecting the attempt to adopt a more context-specific perspective. Even if regulatory acts in this area are quite limited at the national level,[62] some legal systems have started drafting a regulatory framework for the use of AI in the therapeutic relationship, taking into account both pros and cons of its application. More precisely, two legal systems need to be analysed because of their legislative choice in regulating the use of AI systems within the doctor-patient relationship: France and Italy. These two legal systems have chosen to regulate AI, paying attention also on possible effects of the use of AI in this specific domain, through the adoption and proposal of legislative acts, considering this kind of source of law an important safeguard for its effective enforcement.[63] But, besides that, these normative acts also differ in their contents and potential scope.

In France, before the approval and entry into force of the AI Act, the legislature introduced rules concerning the application of AI in the medical field within the *Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique*. This Act reviews the French regulatory framework on bioethics, health rights, and the care relationship, pursuing the goal of achieving an updated legislation in line with the scientific and technological progress.[64] For this reason, the French Parliament decided to introduce some rules on

[61] The need to inform patients about the use of AI systems during the therapeutic process is affirmed by M. KIENER, *Artificial intelligence in medicine and the disclosure of risks*, in *AI & Society*, 3, 2021, 705-713. Contrary to this position cf. I.G. COHEN, *Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?*, in *The Georgetown Law Journal*, 108, 2020, 1425-1469.

[62] See K. PALANIAPPAN, E.Y.T. LIN, S. VOGEL, *Global regulatory Framework for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector*, in *Healthcare*, 5, 2024, 1-12.

[63] In the first two cases, we are talking about hard law tools, whereas in the third case, AI regulation is established through soft law instruments. The key difference between these regulatory approaches lies in the legal binding level of the implemented tools. On the policy choices concerning the regulation of AI in medicine cf. A. ESSÉN ET AL., *Health app policy: international comparison of nine countries' approaches*, in *npj Digital Medicine*, 31, 2022, 1-10.

[64] Since 2011, the French Parliament is required to assess every seven years whether the *Loi de bioéthique* should be revised and amended and, to this end, to convene the *États généraux de la bioéthique*. This approach ensures that the law is updated in light of scientific and technological advancements while also addressing the participation of civil society to the public debate on ethically controversial issues. See J.R. BINET, *La réforme de la loi bioéthique: commentaire et analysede la loi n. 2011-814 du 7 juillet 2011 relative à la bioèthique*, Paris, 2012; B. REBER, *Introduction. Analyses des États Généraux de la Bioéthique*, in *Archives de Philosophie du Droit*, 53, 274-

the use of AI in the medical field within this law. However, it is important to note that the *Loi n° 2021-1017* does not serve as a regulation exclusively focused on the implementation of AI in the therapeutic relationship.[65] Nevertheless, Article 17 of the legislative act provides some relevant obligations concerning the use of this technology. Specifically, this provision, which amends Article L. 4001-3 of the *Code de la santé publique*, requires that healthcare professionals using AI systems for diagnostic, treatment, or prevention purposes must inform the patient about the AI's use and the interpretation of its results.[66] Additionally, healthcare professionals must be informed about the use of these systems, and, thus, have access to the patient data used during the processing and to the results obtained.[67] Then, the *Loi n° 2021-1017* states that designers of the AI systems must ensure their explicability, to make the final users able to properly understand how the AI system works. and ensure that the operation of the AI systems is explainable to them.[68]

These provisions aim at clarifying which are the safeguards applicable to AI in the therapeutic context, emphasizing the importance of transparency and information to minimize opacity and automation bias risks. Following this purpose, the French legislation recognises patients' right to be informed about AI application and its outputs' interpretation, thus enhancing patients' right to know all the relevant data to make an informed decision. This means that physician and healthcare professionals must be not only aware of AI implementation within the therapeutic relationship, but also able to understand AI functioning and its decision logic. In these terms, the French regulation, while not an organic one regarding this field, provides legal tools which enhance the scope and the effectiveness of patients' informed consent when facing AI tools. Additionally, the new provision recognises the guarantee of human control over AI operations within the doctor-patients relationship, avoiding the risk of the patient being entirely alone when interacting with the AI and its outcomes.[69]

285. On the opportunity of using such kind of instruments to frame timely and tuned regulatory frameworks cf. C. CASONATO, *21st Century BioLaw: a proposal*, in *BioLaw Journal – Rivista di BioDiritto*, 1, 2017, 87 ff.

[65] *Comité Consultatif National d'Éthique, Comité National Pilot d'Éthique du Numérique, Joint Opinion. Opinion No. 141 CCNE, Opinion No. 4 CNPEN. Medical Diagnosis and Artificial Intelligence. Ethical Issues*, 24 November 2022, 41 ff.

[66] Art. L. 4001-3(I), Code de la santé publique as amended by art. 17, Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique.

[67] Art. L. 4001-3(II), Code de la santé publique as amended by art. 17, Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique.

[68] Art. L. 4001-3(III), Code de la santé publique as amended by art. 17, Loi n° 2021-1017 du 2 août 2021 relative à la bioéthique.

[69] See C. GAUTHIER-MAXENCE, *Défis Juridiques du Droit de la Santé à l'ère du numérique et de l'IA*, 25 June 2024, in https://www.village-justice.com/articles/evolution-droit-sante-avec-numerique-intelligence-artificielle-adaptations,50148.html (last accessed 19/01/2025); *Étude d'impact. Projet de loi relatif à la bioéthique*, 23 July 2019, 82 ff., in https://www.legifrance.gouv.fr/contenu/Media/Files/autour-de-la-loi/legislatif-et-reglementaire/etudes-d-impact-des lois/ei_art_39_2019/ei_ssax1917211l_bioethique_cm_24.07.2019.pdf (last accessed 19/01/2025); *Conseil D'état*, *Avis sur un projet de loi relatif à la bioethique*, 18 July 2019, 20, in https://www.legifrance.gouv.fr/contenu/Media/Files/autour-de-la-loi/legislatif-et-reglementaire/avis-du-ce/2019/avis_ce_ssax1917211l_pjl_bioethique_cm_24.07.2019.pdf (last accessed 19/01/2025); C. LEQUILLERIER, *L'impact de l'IA sur la relation de soin*, in *Journal de Droit de la Santé e de l'Assurance Maladie*, 25, 2020, 84-91; C. MANAOUIL, S. CHAMOT, P. PETIT, *La médicine confronté à l'IA (Intelligence artificielle): Éthique et responsabilité*, in *Médicine & Droit*, 186, 2024, 50-66.

In Italy, the regulatory landscape for AI is currently lacking specific national legislative acts.[70] However, a recent bill introduced in the Italian Parliament aims to regulate the application of AI across various fields, including healthcare. The proposed legislation, known as the *Disegno di legge disposizioni e delega al Governo in materia di intelligenza artificiale*, seeks to align Italian regulatory framework with the AI Act one and to govern the use of AI in key areas.[71] In these terms, the Italian proposal differs from the French regulation. While the latter is a legislative act aimed at ruling people's rights and duties on the medical domain, so including some provisions on the implementation of AI, the Italian act is completely focused on AI regulation, taking into account medicine as one of the most promising fields of its implementation.[72] More precisely, the Italian bill acknowledges AI's potential to enhance the national healthcare service, prevention, and treatment pathways while safeguarding individual rights and freedoms.[73] For this reason, the proposal affirms that AI implementation cannot select or determine access to healthcare service according to discriminatory criteria.[74] The provision focuses specifically on aspects of the doctor-patient relationship. Once approved, the bill aims to establish individuals' right to be informed about the use of AI, as well as the diagnostic and therapeutic benefits that stem from this technology. It also emphasizes the importance of understanding the rationale behind AI decision-making processes.[75] The bill clearly states that the final medical decisions must remain the responsibility of healthcare professionals, ensuring that AI systems play a supportive role in prevention, diagnosis, treatment, and therapeutic choices.[76] Lastly, it mandates that AI datasets must be reliable, periodically verified, and updated to minimize the risk of errors.[77]

[70] Although there is currently a regulatory vacuum in the field, Italian case law has significantly contributed to establishing some general principles regarding the use of AI. In the context of the judicial strand related to the "Buona Scuola" case, the *Consiglio di Stato* outlined rules for applying AI in administrative proceedings, foreshadowing some of the obligations later introduced by the AI Act.

[71] On this proposal see B. Romano, *Il DDL in materia di IA: l'utilizzo nell'attività giudiziaria e in ambito sanitario*, in *Rivista Italiana di Medicina Legale (e del Diritto in campo sanitario)*, 1-2, 2024, 409 ff. This rationale is expressed by art. 1, Disegno di legge disposizioni e delega al Governo in materia di intelligenza artificiale. In this way, the proposal aims at promoting a correct, transparent an anthropocentric use of AI, ensuring the oversight of its social and economic risk which could affect fundamental rights. It is important to note that art. 1(2) establishes that the interpretation and the implementation of the proposal must be in accordance with the EU law, trying to avoid any possible overlapping with the Regulation (EU) 2024/1689. Recently, the European Commission has expressed its opinion on this draft bill, showing concern over the choice of the Italian Cabinet to assign to governmental bodies the task to oversee AI applications, instead of independent authorities. On this aspect cf. F. Pizzetti, *IA, perchè l'Europa fa bene a bocciare la legge italiana*, 13 December 2024, in https://www.agendadigitale.eu/sicurezza/privacy/lue-boccia-il-ddl-ia-italiano-pizzetti-errore-strategico-la-vigilanza-nazionale/ (last accessed 20/01/2025).

[72] B. Romano, *op. cit.*, 413 ff.; S. Pillon, *Ddl IA, tanti passi avanti in Sanità digitale: eccoli*, 26 April 2024, in https://www.agendadigitale.eu/sanita/ia-in-sanita-tutti-i-passi-avanti-del-disegno-di-legge/ (last accessed 20/01/2025).

[73] Art. 7(1), Disegno di legge disposizioni e delega al Governo in materia di intelligenza artificiale. So, for example, the Italian bill states the need to safeguard the right to privacy and to data protection when using AI within the medical field.

[74] Art. 7(2), Disegno di legge disposizioni e delega al Governo in materia di intelligenza artificiale.

[75] Art. 7(3), Disegno di legge disposizioni e delega al Governo in materia di intelligenza artificiale.

[76] Art. 7(5), Disegno di legge disposizioni e delega al Governo in materia di intelligenza artificiale.

[77] Art. 7(6), Disegno di legge disposizioni e delega al Governo in materia di intelligenza artificiale.

The Italian bill, like the French Act, aims to clarify the scope of enforceable safeguards regarding the use of AI in healthcare. It defines doctors' and patients' duties and rights in this context. The proposal recognizes patients' right to be informed about the use of AI systems in diagnostic and therapeutic processes, emphasizing the importance of this information in preserving patients' decision-making autonomy. Additionally, it includes the patient's right to understand the decision-making logic behind the AI systems used, which enhances individual awareness of how AI functions. This focus on transparency is intended to improve the doctor-patient relationship and strengthen the guarantees that protect the right to informed consent.

Furthermore, the bill provides that healthcare professionals should retain exclusive decision-making authority, classifying AI systems as instrumental and supportive tools. This represents a significant safeguard within the therapeutic relationship. Unlike the French regulation, the Italian legislative proposal specifically provides an essential measure against the risk of automation bias. It designates doctors and healthcare professionals as responsible for overseeing the impact of AI outcomes on patients' health,[78] complementing the human oversight requirement provided by the AI Act.[79]

4. The multilevel and multisource regulation of AI in the doctor-patient relationship. A path to promote potentialities and fill in the gaps

The different regulatory approaches to AI in healthcare in France and Italy highlight a complex legal framework that may have specific gaps, potentially undermining the protection of fundamental rights. In this context, Regulation (EU) 2024/1689 is a significant step forward in AI regulation, providing a general framework of rules designed to ensure clarity and certainty in the protection mechanisms and obligations related to AI development and use. However, the broad nature of the Act may limit its effectiveness in addressing specific applications, such as those involving the therapeutic relationship. While the guarantees set forth in the AI Act can help reduce transparency issues and mitigate automation bias in healthcare, uncertainties remain about how these rules will be specifically applied. Therefore, it is essential to coordinate EU-level regulations with national ones to ensure comprehensive protection.[80]

To achieve this, legal interpretation will be crucial in clarifying the provisions of the AI Act and their practical implications. Additionally, national regulations, such as those in France and Italy, can complement the AI Act by addressing specific aspects related to the therapeutic relationship. For example, French and Italian laws provide clearer guidelines on the information that patients must receive and

[78] For a general overview of these regulatory contents see *Dossier XIX Legislatura. Disposizioni e deleghe al Governo in materia di intelligenza artificiale (A.S. n. 1146)*, 11 June 2024, in https://www.senato.it/service/PDF/PDFServer/BGT/01419908.pdf (last accessed 20/01/2025).

[79] In this way, the Italian proposal clearly outlines the obligation doctors have concerning the oversight of AI-generated results. In contrast, the AI Act provides vague guidance on who is required to ensure human oversight. Based on the definition of "deployer" in Regulation (EU) 2024/1689, it can be inferred that doctors and healthcare organizations may both fall under this obligation.

[80] On the general implementation of the AI Act and its enforcement at the national level see C. Cancela-Outeda, *The EU's AI act: A framework for collaborative governance*, in *Internet of Things*, 27, 2024, 1-11; K. Söderlund, S. Larsson, *Enforcement Design Patterns in EU Law: An Analysis of the AI Act*, in *Digital Society*, 3, 2024, 1-21.

ISSN 2284-4503

the extent of control that healthcare professionals have over AI-generated decisions. Coordinating supranational and national regulations can enhance the protection of fundamental rights in specific areas, including healthcare, while also leveraging the interpretative roles of national and supranational courts.

Despite the potential benefits of a multilevel regulatory approach,[81] concerns exist regarding gaps in EU and national regulations that could hinder the effective implementation of the prescribed obligations. At the EU level, ambiguities arise concerning the practical implementation of measures, the identification of AI deployers, and the guarantees applicable to patients interacting with AI systems for therapeutic purposes. At the national level, there are shortcomings in clarifying healthcare professionals' decision-making responsibilities and in fully informing patients about the risks and benefits of AI. French and Italian laws, in particular, lack detailed specifications regarding the obligation to provide information and the patient's right to consent to or refuse the use of AI in treatment.[82] Moreover, the national regulations reviewed lack clarity on key elements that could prevent the emergence of a new form of technological paternalism. For instance, French regulations do not specify healthcare professionals' duty to oversee the application of AI systems within the therapeutic relationship, allowing for their use without proper oversight. A similar oversight is present in Italian legislation, which mandates informing patients only about the benefits of AI systems, omitting information about potential risks. These gaps may undermine the protection of individuals' fundamental rights in the face of opacity and the risks associated with automation bias, underscoring the need for further regulatory interventions. Therefore, the AI regulatory process is far from complete, particularly regarding AI Act, and further regulatory measures are required to address these loopholes. Supplementing the law with technical standards, guidelines, codes of medical ethics, and other soft law instruments will be crucial to defining the requirements for developing and using AI. The importance of such regulatory instruments in the care relationship is already evident when analysing their adoption at international, supranational, and national levels.

In this context, the World Health Organization (WHO) plays a crucial role in establishing ethical and legal guidelines regarding the implications of using artificial intelligence (AI) in medicine, as well as recommendations for effective technology governance.[83] The decision to develop specific guidelines for large multi-modal models further emphasizes the significance of these soft law tools and their regulatory complementarity.[84]

---

[81] I. Pernice, *Multilevel constitutionalism in the European Union*, in *European Law Review*, 5, 2002, 511 ff.; G. Martinico, *Complexity and Cultural Sources of law in the EU Context: From the Multilevel Constitutionalism to the Constitutional Synallagma*, in *German Law Journal*, 3, 3007, 205-227; N. Chowdhury, R.A. Wessel, *Conceptualising Multilevel Regulation in the EU: A Legal Translation of Multileve Governance?*, in *European Law Journal*, 3, 2012, 335-357.

[82] The possibility of recognising a right to AI has been theorised in C. Casonato, *Unlocking the Synergy: Artificial Intelligence and (old and new) Human Rights*, cit., 239 ff.

[83] World Health Organization (WHO), *Ethics and Governance of Artificial Intelligence for Health. WHO guidance*, cit., 1 ff. Also cf. M. Daverio, F. Macioce, *Intelligenza artificiale e diritto alla salute nella regolazione europea: aspetti emergenti riguardo alla relazione medico-paziente*, in *Teoria e critica della regolazione sociale*, 2023, 96 ff.

[84] World Health Organization (WHO), *Ethics and governance of artificial intelligence for health. Guidance on large multi-modal models*, cit., 1-77. On the problematic issues arising from the regulation of this specific AI model see

The importance of atypical regulatory instruments becomes even more evident at the supranational level.[85] The AI Act specifies that harmonized standards will be adopted and implemented to clarify the requirements for high-risk AI systems, integrating them into the conformity assessment process.[86] Additionally, the Regulation (EU) 2024/1689 grants the European Commission the authority to adopt delegated acts that will supplement the applicable rules and guidelines, that aims to assist stakeholders in understanding and complying with the requirements of the AI Act.[87] For these reasons, Recently, the European Commission has issued guidelines that clarify the meaning of AI definition and explain prohibited AI practices. These guidelines are intended to provide clarity on the Act's interpretation and to ensure consistent, uniform, and effective application of its provisions.[88]

Finally, some national legal systems use guidelines and technical standards as the main regulatory tools to govern AI in the medical field. This is, for example, the situation in the United States, where the field of medical IA mostly relies on a set of guidelines approved by the Federal Drug Administration, concerning the development and the production of AI systems as medical devices.[89]

However, reliance on flexible and technical normative sources raises important questions about how to balance legal, scientific, and technological domains when it comes to protecting fundamental rights. It is crucial to assess whether delegating essential regulatory aspects, such as the right to use or refuse AI, to less binding legal sources or private entities could compromise individual rights in favour of the

G. De Minico, *Too many rules or zero rules for the ChatGpt?*, in *BioLaw Journal – Rivista di BioDiritto*, 2, 2023, 491 ff.

[85] R. Bibier, I. Salomé, *Hierarchy of Norms in European Law*, in *Common Market Law Review*, 5, 1996, 909 ff.; F. Snyder, *Soft Law and Institutional Practice in the European Community*, in S. Martin (ed.), *The Construction of Europe. Essays in Honour of Emile Noël*, Cham, 1994, 197-225; L. Senden, *Soft Law in European Community Law*, Oxford-Portland, 2004; A. Peters, *Soft Law as a New Mode of Governance*, in U. Diedrichs, W. Reiners, W. Wessels (eds.), *The Dynamics of Change In EU Governance*, Cheltenham, 2011, 21-51.

[86] Article 40, Regulation (EU) 2024/1689. Generally, on technical standards cf. M. Eliantonio, C. Cauffman, *The Legitimacy of Standardisation as a Regulatory Technique in the EU – A Cross-disciplinary and Multi-level Analysis: An Introduction*, in M. Eliantonio, C. Cauffman (eds.), *The Legitimacy of Standardisation as a Regulatory Technique*, Cheltenham, 2020, 1-18, and on the role they have within the AI Act cf. A. Iannuzzi, *Le fonti del diritto dell'Unione europea per la disciplina della società digitale*, in F. Pizzetti (ed.), *La regolazione europea della società digitale*, Turin, 2024, 31 ff.

[87] Art. 96, Regulation (EU), 2024/1689; art. 97, Regulation (EU) 2024/1689.

[88] See European Commission, *Communication to the Commission. Approval of the content of the draft Communication from the Commission – Commission Guidelines on prohibited artificial intelligence practices established by Regulation (EU) 2024/1689 (AI Act)*, Brussels, 4 February 2025, at https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-prohibited-artificial-intelligence-ai-practices-defined-ai-act (last accessed 05/03/2025); European Commission, *Communication to the Commission. Approval of the content of the draft Communication from the Commission – Commission Guidelines on the definition of an artificial intelligence system established by Regulation (EU) 2024/1689 (AI Act)*, Brussels, 6 February 2025, at https://digital-strategy.ec.europa.eu/en/library/commission-publishes-guidelines-ai-system-definition-facilitate-first-ai-acts-rules-application (last accessed 05/03/2025)

[89] The FDA guidelines are listed in the following website https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device (last accessed 20/01/2025). They concern the development and production of AI systems as medical devices. In Italy, a process to reform the medical ethics code is currently underway, which will result in the adoption of a new code that includes regulations on the use of AI. On this topic cf. *Verso il nuovo Codice deontologico. Fnomceo: "AI via i lavori su 4 direttrici. Aperti al confronto anche con società civile*, 3 February 2023, in https://www.quotidianosanita.it/lavoro-e-professioni//articolo.php?articolo_id=110814 (last accessed 20/01/2025).

interests of the technology industry. Therefore, it is vital to ensure that traditional and typical legal sources maintain their regulatory role in order to uphold fundamental rights and freedoms in the ever-evolving landscape of technological innovation.[90]

[90] A. IANNUZZI, *Paradigmi normativi per la disciplina della tecnologia: auto-regolazione, co-regolazione ed etero-regolazione*, in *Bilancio, Comunità, Persona*, 2, 2023, 100 ff. For a critique of the increasing use of atypical sources of law see, among Italian legal scholars, R. BIN, *Critica della teoria delle fonti*, Bologna, 2021.