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# TECHNOPOLITICS

**Charting the unknown**



**Edited by Constantino Pereira Martins**



**DIALÉTICA**  
EDITORA



**ETHICS, LAW, AND REGULATION  
OF ARTIFICIAL INTELLIGENCE  
IN MEDICINE**

**Zaouaq Karim**



# ETHICS, LAW, AND REGULATION OF ARTIFICIAL INTELLIGENCE IN MEDICINE

Zaouaq Karim

## INTRODUCTION

In medicine, AI is gaining ground and is already employed by healthcare providers. Machine learning, process automation, robotics, and natural language processing (NLP) systems, along with other AI-related technologies, are frequently used in the medical field to process patient notes, create reports, and record doctor-patient interactions. It's even predicted that the large-scale use of AI will make the medical field more automated, and algorithms are likely to replace medical practitioners in the future, especially in radiology. Regarding that, a prominent researcher in AI has proposed that “we should stop training radiologists for the future, as we will soon be superseded in performance by AI”<sup>1</sup>.

AI applications in the medical field are numerous. But there are particular applications of AI depending on the technology used. With machine learning, AI algorithms can be used for predicting, diagnosing diseases, taking decisions based on complex combinations of variables, as well as “predicting what treatment protocols are likely to succeed on a patient based on various patient attributes and the treatment context”<sup>2</sup>.

In terms of automated image-based diagnosis, radiologists, ophthalmologists, dermatologists, and pathologists are currently the ones who rely on AI technologies the most. In radiology, for instance, applications of artificial intelligence such as “the detection of lung nod-

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1 Geoff Hinton, “On Radiology”, YouTube, November 24, 2016, video, 1:24. <https://www.youtube.com/watch?v=2HMPRXstSvQ>. See also: Adrian P. Brady and Emanuele Neri, “Artificial Intelligence in Radiology—Ethical Considerations”, *Diagnostics* 10, no. 4 (2020): 231, <https://doi.org/10.3390/diagnostics10040231>

2 Thomas Davenport and Ravi Kalakota, “The potential for artificial intelligence in healthcare”, *Future Healthcare Journal* 6, No. 2 (2019): 94. DOI: 10.7861/futurehosp.6-2-94.

ules, the diagnosis of pulmonary tuberculosis, and breast mass identification have reached expert level diagnostic accuracy”<sup>3</sup>, particularly in malignant tumor spotting, upon which algorithms overcome radiologist’s capacities and are likely to replace human intelligence in this field. In addition, AI makes it possible to identify potentially cancerous lesions in radiology images through “the application of neural network models with many levels of features or variables that predict outcomes”<sup>4</sup>.

Similarly, machine learning technology has been used for years to predict if a patient will contract a specific disease. On this point, it has been shown that the algorithms were able to “predict and diagnose diseases, from cardiovascular illnesses to cancer, and predict related things such as the likelihood of death, the length of hospital stay, and the chance of hospital readmission”<sup>5</sup>. Based on video analysis, AI can also determine patient health indicators, such as “pressure, pulse, breathing rate, and stress level”<sup>6</sup>. These metrics will serve to detect “patterns that indicate disease long before obvious symptoms appear”<sup>7</sup> as well as the disease symptoms.

Additionally, during the COVID-19 epidemic, AI was utilized to assess people’s temperatures and determine who has a fever in real-time using a mix of infrared cameras and remote sensors.

This paper discusses the ethical and legal challenges raised by artificial intelligence in Medicine before highlighting the attempts made to regulate AI technology’s uses and their limitations.

## **I. USING ARTIFICIAL INTELLIGENCE IN MEDICINE: ETHICAL AND LEGAL CHALLENGES**

Artificial intelligence has tremendous potential in improving medical practice, but it presents numerous ethical and legal challenges.

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3 Maximillian Samuel Thompson and James W Ternent. 2020. *Ethical Considerations of Artificial Intelligence Via Neural Networks Applied to Medical Applications*: Worcester Polytechnic Institute.

4 Thomas Davenport and Ravi Kalakota, “The potential for artificial intelligence in healthcare”, *op. cit.*, 94.

5 Tim Dare, “Ethics of artificial intelligence and health care”, *The New Zealand Medical Student Journal*, Issue 28 (June 2019): 6.

6 Olena Yara et al. “Legal Regulation of the Use of Artificial Intelligence: Problems and Development Prospects”, *European Journal of Sustainable Development* 10, 1 (2021): 284. Doi: 10.14207/ejsd.2021.v10n1p281

7 *Ibid.*

## A. Ethical challenges

Although there are many ethical guidelines that protect patients' rights, these standards might be challenged by the issues raised by AI.

A study revealed that algorithms were used to help health systems target patients with healthcare needs, predicting how many of them will resort to medical services and generate extra costs in the future<sup>8</sup>, as was the case with the U.S. healthcare system, which used commercial algorithms to guide health decisions<sup>9</sup>. In the same study, evidence was found of racial bias in one widely used algorithm, “such that Black patients assigned the same level of risk by the algorithm are sicker than White patients”<sup>10</sup>. Authors estimated that this racial bias occurs because “the algorithm uses health costs as a proxy for health needs, and for predicting who needs extra care”<sup>11</sup>.

AI can be a source of bias based on sex, gender, and even ethnicity, and religion and can generate discriminatory behaviors. In this regard, bias can occur with the misinterpretation of the data collected on the representation of ethnic, social, and cultural minorities from their medical records. Errors of interpretation may occur too “if these data are not very representative or skewed”<sup>12</sup>.

AI undermines privacy and is likely to turn patients into mere data, posing the risk of dehumanization. Similarly, there is skepticism about AI's ability to take into consideration environmental, social, and cultural factors impacting patients, as well as their moral and value standards.

AI can make mistakes, and the decisions it makes are hardly explainable to patients, resulting in the ethical challenge of the lack of transparency. This is more likely to occur in the cases of the so-called “black box” models, which refer to AI models that are too

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8 Ziad Obermeyer, et al. “Dissecting racial bias in an algorithm used to manage the health of populations”, *Science* 366, Issue 6464 (2019): 447-453. <https://doi.org/10.1126/science.aax2342>.

9 *Ibid.*

10 *Ibid.*

11 *Ibid.*

12 Erito Marques de Souza Filho, et al. “Ethics, Artificial Intelligence and Cardiology”, *Arquivos Brasileiros de Cardiologia* 115, 3 (2020): 580.

complex for humans to understand and which require “post hoc explainability for how results are produced”<sup>13</sup>.

The lack of transparency is relevant in some complex medical situations where black box algorithms are used, as is the case in diagnosing certain diseases such as “diabetic retinopathy, glaucoma, age-related macular degeneration, and retinopathy of prematurity”<sup>14</sup>, or in relation to the mechanism of action of some drugs.

The issue of transparency also arises when AI systems provide false, nonsense, or inaccurate answers, resulting in patient misdiagnosis, and the same issue will persist even if the patient seeks a second opinion, because if an algorithm is widely used among medical hospitals and professionals, “the same system may be performing the diagnosis at a separate clinic”<sup>15</sup>.

That is why we should not completely trust AI algorithms, and the emphasis should be on inventing and developing AI models that are explainable and interpretable, rather than ones that are inexplicable and complex. It is also critical that “the algorithms be audited periodically and that their performance metrics be informed to patients before making any decisions regarding their health”<sup>16</sup>.

Furthermore, many medical organizations use Chatbots as a tool to improve communication between patients and doctors and help them connect. However, Chatbots, which can be useful for administrative tasks such as filling prescriptions or making appointments, raise ethical concerns regarding patient-doctor interactions. For instance, “in a survey of 500 US users of the top five chatbots used in healthcare, patients expressed concern about revealing confidential information, discussing complex health conditions, and poor usability”<sup>17</sup>.

In this regard, digital health, e-health, and telemedicine are beneficial tools as they help to supply more healthcare services, but they

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13 Nicholas G. Evans, et al., “Emerging Ethical Considerations for the Use of Artificial Intelligence in Ophthalmology”, *Ophthalmology Science* 2, No. 2 (June 2022): 1. DOI: 10.1016/j.xops.2022.100141.

14 *Ibid.*

15 *Ibid.*

16 Erito Marques de Souza Filho, et al., “Ethics, Artificial Intelligence and Cardiology”, *op. cit.*, 580-581.

17 Thomas Davenport and Ravi Kalakota, “The potential for artificial intelligence in healthcare”, *op. cit.*, 96.

raise ethical concerns related to the doctor-patient relationship. In fact, the virtualization of the doctor-patient relationship poses the risk that “the doctor who becomes “virtual” is not lessened and comprehended by the “virtual” patient”<sup>18</sup>. This virtualization frequently affects the human doctor-patient relationship and can impact the health status of the latter, especially if he or she is suffering from a chronic illness<sup>19</sup>.

The deployment of AI technologies requires intensive resources for data management and access to AI solutions. Inequalities in resources between regions, countries, social groups, and individuals can then lead to unfairness, especially in countries whose health systems are lacking in resources, as is the case in most of the Global South countries. In those countries, healthcare systems will be hardly able to “ensure that the benefits of AI are delivered to all patients they serve, not just to those with access to greater resources”<sup>20</sup>.

## **B. Legal challenges**

Among the main legal challenges that arise with the application of IA to health issues, we can emphasize the fundamental concern related to the obligation to provide patients with full, clear, and comprehensible information. Algorithms are likely to undermine these legal requirements, along with the free, prior, and informed consent principle. For example, it may not be possible for humans to “explain, or even to know, why a complex machine learning system has classified a case one way rather than another”<sup>21</sup>. AI algorithms, especially those that are used to analyze images, are impossible to explain or interpret. If an image analysis leads to a diagnosis that pronounces the presence of cancer, the patient will eventually require explanations around this conclusion. However, even physicians who are familiar with these AI technologies, will not be able to explain such images.

There are also risks that hover today over medical data in an era where information systems are struggling to perform effectively,

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18 Karim Zaouaq, “La télé-médecine et ses implications sur la relation médecin-patient”, *Journal international de bioéthique et d'éthique des sciences* 33, no. 2 (2022) : 17.

19 *Ibid.*

20 Adrian P. Brady, and Emanuele Neri, “Artificial Intelligence in Radiology—Ethical Considerations”, *op. cit.*, 5.

21 Tim Dare, “Ethics of artificial intelligence and health care”, *The New Zealand Medical Student Journal*, *op. cit.*, 6.

because of the drifts associated with data entry errors, and malicious attempts to steal and manipulate personal data<sup>22</sup>.

Furthermore, AI systems may make errors in the treatment, diagnosis, and detection of patient medical issues, raising the legal question of liability and responsibility. If an AI decision ends in a mistake or a bad outcome, the question is who is responsible, whether it is the physician who employs AI technology, the developer who built it, or the medical entity that purchases it.

## **II. THE REGULATION OF ARTIFICIAL INTELLIGENCE IN MEDICINE: THE ROLE OF LAW AND ETHICS**

Besides ethical principles whose implementation can frame artificial intelligence practice, many international organizations and States have enacted public policies and frameworks to better regulate artificial intelligence uses in Medicine, despite their limited effectiveness.

### **A. Framing artificial intelligence through ethical principles**

The ethical concerns posed by AI in medicine can be overcome by adhering to some key principles, including the four principles outlined by Beauchamp and Childress in their book “Principles of Biomedical Ethics”: autonomy, beneficence, nonmaleficence, and justice. Each principle helps healthcare professionals in making decisions. Autonomy refers to the patient’s ability to make decisions concerning his own body and personal health information. Beneficence is realized when the benefits to the patient are greater than the risks. Nonmaleficence implies that medical professionals should not harm patients. Likewise, justice tackles “the question of who receives healthcare resources as they are in scarce supply”<sup>23</sup> and means that health systems need to ensure that both benefits and harms are fairly distributed among the impacted population.

Besides these broad concepts, additional ethical principles and standards derived from the bioethics register can assist in addressing the issues posed by AI in medicine. Privacy, human dignity, informed consent, safety, transparency, equality, and social accep-

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22 Karim Zaouaq, “La télé-médecine et ses implications sur la relation médecin-patient”, *op. cit.*, 18.

23 Dana J. Lawrence, “The four principles of biomedical ethics: a foundation for current bioethical debate”, *Journal of Chiropractic Humanities* 14 (2007): 34-40.

tance are at the forefront of these values, as are algorithmic fairness, scientific validity, and public benefit.

Ethical principles guide behavior and actions in complex medical situations, and they should serve as a foundation for any legal, social, or moral rules that regulate AI systems and the organizations that deploy and develop them.

For instance, doctors should obtain the consent of their patients and inform them on the benefits, risks, intentions, and suitable outcomes driven by the use of automated systems for their diagnosis, and treatment. They should also try to understand the decision made by an automated AI system on the diagnosis and treatment of the patient and build their own clinical judgment without entirely trusting the AI system. This will enable them to avoid, to a greater extent, a misdiagnosis that can be led by mistakes made by AI systems.

Ensuring transparency requires vigilance in designing automated systems so that “algorithmic decisions can be explained to end-users and stakeholders”<sup>24</sup>. This cannot happen without making AI systems more explainable and interpreted and finishing with the black box algorithms, which “do not allow us to see how the machine has arrived at the decision”<sup>25</sup>. AI organizations should also ensure the explicability, traceability, and understandability of the data used, as well as their quality, which should be guaranteed through a continuous assessment and auditing of their availability, regularity, clarity, and privacy.

Furthermore, justice and fairness principles must be considered while creating AI systems to avoid any unjust or biased actions that could worsen the health issues of marginalized groups, minorities, disabled individuals, or people with mental illnesses.

## **B. Regulation of artificial intelligence in medicine: scope and limits of the existing legal framework**

Along with the policies implemented in many nations to develop AI<sup>26</sup>, standards, and regulations were adopted at the international, regional,

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24 Sandra L J Johnson, “AI and machine learning in medicine: ethical considerations”, *Current Allergy & Clinical Immunology* 33, No 2, (June 2020): 116.

25 *Ibid.*

26 Such as Canada, China, Denmark, Finland, France, India, Italy, Japan, Mexico, Singapore, South Korea, Sweden, Taiwan, the United Arab Emirates, Russia, and Great Britain. See Aleksey Vladimirovich Minbaleev, Tatyana Anatolyevna Polya-

and national levels to guide the use of such technology in various disciplines, including medicine.

Thus, in addition to the Universal Declaration on Bioethics and Human Rights adopted on October 19, 2005, which contains general ethical principles applicable to all life sciences and technologies, including telemedicine, 193 Member States at UNESCO's General Conference adopted in November 2021 the Recommendation on the Ethics of Artificial Intelligence, the very first universal standard-setting instrument on the subject. It protects and promotes human rights and human dignity, and represents "an ethical guiding compass and a global normative bedrock allowing to build strong respect for the rule of law in the digital world"<sup>27</sup>.

Furthermore, the Montréal Declaration for Responsible AI Development and the Asilomar AI Principles provide a universal ethical framework for AI applications by enunciating essential AI-related ethical principles such as beneficence, nonmaleficence, autonomy, justice, and explainability.

The OECD established a model that governs AI applications in relation to machine learning systems. This model sets up requirements for combating bias and enhancing algorithmic accountability, as well as a "security-safety-security" approach<sup>28</sup>. Following that, the OECD adopted on May 22, 2019, a Recommendation on Artificial Intelligence (AI), which has set five values-based principles for responsible stewardship of trustworthy AI, including sustainable development, and well-being; human-centered values and fairness; transparency and explainability; robustness, security, and safety; and accountability"<sup>29</sup>. Thus, the OECD first states that AI should pursue beneficial outcomes for people and the planet by invigorating inclusive growth, sustainable development, and well-being. Second, human-centered-values and human rights should be respected throughout the AI system lifecycle, including freedom, dignity, autonomy, privacy and data protection, nondiscrimination and

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kova, and Oleg Sergeevich Makarov, "Problems of ethical regulation of the use of artificial intelligence technologies", SHS Web of Conferences 118, RUDN LTMRP Conference 2021.

27 see <<https://www.unesco.org/en/artificial-intelligence/recommendation-ethics>>.

28 OECD, "The technical landscape", in *Artificial Intelligence in Society*, OECD Publishing, Paris, 2019.

29 OECD, Recommendation of the Council on Artificial Intelligence, OECD/LEGAL/0449, file:///C:/Users/Karam/Downloads/OECD-LEGAL-0449-en.pdf

equality, diversity, fairness, social justice, and internationally recognized labor rights. Third, transparency and responsible disclosure should be implemented for the sake of a better understanding of the AI system's outcomes and the logic that served as the basis for the prediction, recommendation, or decision. Fourth, the OECD recommends that AI systems should be robust, secure, and safe and should function appropriately and in a manner that avoids any misuse or safety risk. For this purpose, AI actors are urged to ensure traceability, concerning datasets, processes, and decisions made throughout the AI lifecycle, to assess the AI system's outcomes, and to deploy systematic risk management strategies to tackle any potential risks related to AI systems, including privacy, digital security, safety, and bias. Finally, the OECD urges the stakeholders to make AI actors accountable for the proper functioning of AI systems, in accordance with the above principles<sup>30</sup>.

The most relevant regulations made at a regional scale are those enacted within the European Union. However, most of the European instruments that are related to AI are non-legislative policy instruments and fall into the legal category of soft law. Admittedly, they are numerous and have enshrined many ethical principles and standards, but they are non-binding and do not establish legal obligations. They also lack the means for ensuring the application of their requirements.

The first adopted instrument at the regional European scale was the Statement on Artificial Intelligence, Robotics, and “Autonomous” Systems, established in March 2018 by the European Group on Ethics in Science and New Technologies (EGE), in which four fundamental ethical principles, based on the values laid down in the EU Treaties and the EU Charter of Fundamental Rights were proposed, notably the respect of human dignity, which means that we have to recognize the inherent human state of being worthy of respect, the autonomy which implies the freedom of the human being and the capacity to choose without any coercion or manipulation from Algorithms or machines, the responsibility principle which implies that AI systems should be designed in a way that respects humans rights and values, without posing unacceptable risks to human beings, nor to compromise human autonomy and freedom. The statement also underlines the principles of fairness, justice, equity, and solidarity, which involve fair and equal access to AI benefits, as well as the prevention of discriminatory bias. Besides these principles, the statement puts forward the principle of accountability, which implies clarifying the liability regime and who will

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30 *Ibid.*

lie for undesirable damages caused by autonomous systems; the principles of security, safety, and bodily and mental integrity, which require AI developers to test their applications in order to avoid any infringements on human integrity or on safety and security; and the principle of privacy, which implies the protection of personal data and the right to have a private life, the right to not be profiled, measured, and analyzed.

On April 8, 2019, the High-Level Expert Group on Artificial Intelligence (AI HLEG), whose vocation is to support the implementation of the European Strategy on Artificial Intelligence, published its Ethics Guidelines for Trustworthy AI, which enunciate that a trustworthy AI should be lawful, compliant with all applicable regulations, ethical, and technically robust. The AI HLEG put up key principles for a trustworthy AI, including human agency and oversight, technical robustness and safety, transparency, and traceability of AI systems, non-discrimination, fairness, the well-being of individuals, and accountability for AI systems and their outcomes.

In addition, the European Commission published a Communication on Building Trust in Human-Centric Artificial Intelligence<sup>31</sup> and a White Paper on Artificial Intelligence<sup>32</sup>, aiming to ensure an ecosystem of trust and guarantee compliance with EU rules, including those protecting fundamental rights and consumer rights.

The non-binding nature of these European instruments is tempered by a growing number of other instruments that are legally binding at the European level and that are relevant to the development, deployment, and use of AI systems. These binding instruments include EU primary law (the Treaties of the European Union and its Charter of Fundamental Rights), EU secondary law (such as the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of biology and medicine, the General Data Protection Regulation, the Product Liability Directive, the Directive on Security of Network and Information Systems, the Regulation on the Free Flow of Non-Personal Data, anti-discrimination Directives, consumer law, and Safety and Health at Work Directives), and health specific rules that apply to AI applica-

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31 Communication from the Commission to the European Parliament, the Council, the European Economic, and Social Committee, and the Committee of the Regions - Building Trust in Human Centric Artificial Intelligence (COM(2019)168).

32 White Paper on Artificial Intelligence: a European approach to excellence and trust, launched on 19 February 2020.

tions, such as the Medical Device Regulation in the healthcare sector<sup>33</sup>. For instance, the General Data Protection Regulation (GDPR) established rigorous rules on data protection and privacy, along with transparency and fairness principles. On this subject, Art. 5(1) (a) of the GDPR declares that “personal data shall be processed lawfully, fairly, and in a transparent manner in relation to the data subject”.

At the national level, some countries have established regulatory standards that establish a governance model for AI, while others have done little or nothing to regulate AI applications.

In Singapore, a model of regulation was established and is based on “two main guiding principles: AI decision-making processes must be explainable, transparent, and fair, and AI decisions must be human-centered”<sup>34</sup>.

Likewise, the Singapore Academy of Law put forward various ethical requirements that aim to regulate artificial intelligence<sup>35</sup>, including “consideration of the effects of AI systems; respect for values and culture; management of risks; well-being and safety; accountability; transparency; ethical use of data”<sup>36</sup>.

In Thailand, the Office of the National Digital Economy and Society Commission, Ministry of Digital Economy and Society, published a white paper “Thailand AI Ethics Guideline” which established guidelines to “govern AI technology and realize fairness, transparency, ethical principles, and human rights, reliability, safety, and benefits to human beings, society, and environment”<sup>37</sup>.

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33 Damian Cyman et al., “Regulation of Artificial Intelligence in BRICS and the European Union”, *BRICS Law Journal* 8, 1, (2021): 110.

34 Info-communications Media Development Authority (IMDA) and Personal Data Protection Commission Singapore (PDPC), *Model Artificial Intelligence Governance Framework*, Second Edition, 2020, 15, <https://www.pdpc.gov.sg/-/media/Files/PDPC/PDF-Files/Resource-for-Organisation/AI/SGModelAIGovFramework2.pdf>

35 Singapore Academy of Law. Law Reform Committee. | Simon Constantine, editor, *Applying Ethical Principles for Artificial Intelligence in Regulatory Reform*, (Singapore: Law Reform Committee, Singapore Academy of Law, 2020), ISBN 978-981-14-6600-7.

36 Aleksey Vladimirovich Minbaleev, Tatyana Anatolyevna Polyakova, and Oleg Sergeevich Makarov, “Problems of ethical regulation of the use of artificial intelligence technologies”, *op. cit.*

37 Piyanat Prathomwong and Pagorn Singsuriya, “Ethical Framework of Digital Technology, Artificial Intelligence, and Health Equity”, *Asia Social Issues* 15, No. 5,

In Australia, the Australian Council of Learned Academics (ACOLA) published a white paper on “The effective and ethical development of artificial intelligence”<sup>38</sup>, where they emphasize the ethical, legal, and social considerations and frameworks required to enable and support the broad development of artificial intelligence.

In the UK, the United Kingdom National Health Service (NHS) has adopted a Guide to good practice for digital and data-driven health technologies, which includes a set of principles that apply to AI uses in medicine, notably the definition of the expected outcomes and benefits, lawful data processing, transparency, and evidence of safety and effectiveness<sup>39</sup>.

By contrast to these national models, the USA is known for its minimalist model insofar as it leaves a “large” margin in AI regulation to the private sector itself, especially when it comes to regulating medical uses of AI. Thus, the US Health and Human Services Office of Civil Rights enacts rules related to patient information privacy and security, whereas professional organizations regulate some of the other medical uses of AI. In this regard, the American Medical Association (AMA) issued, in 2018, a policy report<sup>40</sup>, which provided that clinical AI should avoid bias and reflect the principles of transparency, reproducibility, and privacy. Likewise, the American Medical Informatics Association adopted a code of ethics that emphasizes medical ethical principles that should be respected by practitioners and researchers working in the field of biomedical and health informatics<sup>41</sup>.

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(September-October 2022): 12.

- 38 Toby Walsh; Neil Levy; Genevieve Bell, et al. *The effective and ethical development of artificial intelligence: An opportunity to improve our wellbeing* (Melbourne, Victoria: Australian Council of Learned Academia (ACOLA), 2019), <https://acola.org/hs4-artificial-intelligence-australia/>
- 39 UK Department of Health & Social Care, *A Guide to good practice for digital and data-driven health technology* (2021), <https://www.gov.uk/government/publications/code-of-conduct-for-data-driven-health-and-care-technology/initial-code-of-conduct-for-data-driven-health-and-care-technology>
- 40 American Medical Association (AMA), *Augmented intelligence in health care* (2018), <https://www.ama-assn.org/system/files/2019-01/augmented-intelligence-policy-report.pdf>
- 41 Carolyn Petersen, Eta S Berner, Peter J Embi et al., “AMIA’s code of professional and ethical conduct 2018”, *Journal of the American Medical Informatics Association* 25, 11 (November 2018): 1579-1582. DOI: 10.1093/jamia/ocy0920

Whatever the case, most AI regulatory frameworks, both international and regional, are non-binding and remain voluntary. The study of these legal frameworks reveals that liability remains the missing chapter in these instruments.

Liability remains an unanswered question, especially for physicians, and how they can be held legally accountable for a medical decision made based on AI algorithm advice.

Given the complexity of AI systems, courts are likely to rule that algorithms are not legally liable. As a result, clinicians retain complete responsibility for making an accurate and balanced medical judgment.

### CONCLUSION

Today, the use of AI in healthcare delivery offers unheard-of opportunities. However, it is hampered in many nations by inadequate or nonexistent legal and regulatory provisions as well as the lack of suitable safeguards to protect patient rights.

In the face of the myriad risks that may come from the use of AI, fundamental ethical values must prevail, together with binding rules that must provide a clear and acceptable answer to the problems raised by AI.

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