

BULETINUL INSTITUTULUI POLITEHNIC DIN IAȘI
Publicat de
Universitatea Tehnică „Gheorghe Asachi” din Iași
Volumul 70 (74), Numărul 2, 2024
Secția
ELECTROTEHNICĂ. ENERGETICĂ. ELECTRONICĂ
DOI: 10.2478/bipic-2024-0007

ETHICAL CONSIDERATIONS ON ADOPTING ARTIFICIAL INTELLIGENCE ALGORITHMS IN MEDICINE

BY

IRINA PAVEL* and IULIAN B. CIOCOIU

“Gheorghe Asachi” Technical University of Iași, Romania,
Faculty of Electronics, Telecommunications, and Information Technology

Received: June 8, 2023

Accepted for publication: July 11, 2025

Abstract. A faster and smarter healthcare system using artificial intelligence (AI) methods might reliably detect critical diseases, decreasing the patients' waiting period for diagnosis and treatment. When using such tools, ethical issues related to privacy protection have been constantly raised. Fair AI models should avoid any possible source of bias in the datasets under study, while additionally eliminating discrimination against individuals based on their race, sex, religion, and other categories. More specifically, the European Commission and the World Health Organization have generated a corpus of procedures asking AI stakeholders to overcome these challenges in the medical field. Transparency on the data acquisition procedures and equipment, detailed information about how the model has been trained and evaluated, and extended efforts towards explaining how the decisions of the models have been generated are critical if the patients are going to accept these technologies. The paper discusses some of the specific challenges of adopting AI tools within the medical field, focusing on both opportunities and associated limitations and risks.

Keywords: artificial intelligence, trustworthy AI, ethical principles, ethical challenges, medical applications, privacy.

*Corresponding author; *e-mail*: irina.pavel@etti.tuiasi.ro

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1. Introduction

The roots of modern Artificial Intelligence, or AI, can be traced to Greek classical philosophers' attempts to describe human thinking as a symbolic system. Back to the 1950, Alan Turing, a mathematician and computer scientist, wrote a paper proposing a method that tests a thinking machine. But the field of Artificial Intelligence was formally founded in 1956, at a conference at Dartmouth College, in Hanover, New Hampshire, where the term “artificial intelligence” was coined with high costs and limited computer memory (Gaon, 2019; Ali and Byrne, 2023).

Ethics is defined by the Oxford Languages Dictionary as “*moral principles that govern a person's behaviour or the conducting activity*”, or as a “*set of moral principles, especially ones relating to or affirming a specified group, field, or form of conduct.*” More specifically, the ethics of artificial intelligence (AI) is a part of technology ethics (Nyholm, 2022; Braunack-Mayer *et al.*, 2012) which refers to applicative ethics to the practical concerns of a technology that is in full development. It focuses on deciding when it is right or wrong to invent and implement a technological innovation, such as designing a robot, which leads us to robo-ethics. The topic deals with human moral behaviour while designing artificial intelligent beings and the behaviour of artificial moral agents, sometimes thought of as design drivers (Kopacek, 2019). In his famous book *I, Robot*, the science fiction author Isaac Asimov designates the three laws of robotics: “(i) *A robot may not injure a human being or, through inaction, allow a human being to come to harm.* (ii) *A robot must obey orders given it by human beings except where such orders would conflict with the First Law.* (iii) *A robot must protect its own existence as long as such protection does not conflict with the First or Second Law*” (Asimov, 1950).

Artificial intelligence technologies have already shown a remarkable and empowering impact on society, especially in the medical and healthcare industry. Those technologies include machine learning (a subset of AI that uses structured data to learn), and deep learning, a machine learning technique based on neural networks inspired by the human brain. Medical practitioners diagnose patients faster and more accurately, make predictions about the patient's future health status, and find more suitable treatments (Khalifa and Albadawy, 2024). Regardless of how successful this industry might appear, the power of these technologies generates a novel set of ethical challenges that must be taken into account and mitigated concerning the patient's privacy and safety. As developers, by applying an ethical lens we control the design and implementation of novel technologies in order to minimize their potential harm and obey the ethical principles reviewed in this paper.

A definition of AI was proposed by the High-Level Expert Group for Artificial Intelligence (AI HLEG): “*Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a*

complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions” (European Commission and AI HLEG, 2019).

2. European approach to artificial intelligence

In this section, we discuss Europe’s chronological journey from ethical to building trustworthy artificial intelligence systems. A legal framework for AI sets out clarity for developers, deployers, and users to understand the potential associated risks.

In March 2018, the European Commission adopted the AI strategy for Europe by establishing a kick-off commission on artificial intelligence and ethical standards in a press release (European Commission, 2018). In April 2018, 25 European countries signed up a declaration of cooperation on AI ensuring social, economic, ethical, and legal matters (European Commission, 2018). By June 2018, European Commission appointed the AI Alliance and the High-Level Expert Group for Artificial Intelligence to promote “Trustworthy AI” (European Commission, 2022). AI HLEG will be responsible for mid and long-term challenges and digital strategies related to AI, as well as, assisting the European Commission through the community of stakeholders known as the European AI Alliance. In April 2019, AI HLEG issued Ethics Guidelines, after the first version was drafted in 2018, stating that “*Trustworthy AI should be: (1) lawful – respecting all applicable laws and regulations, (2) ethical – respecting ethical principles and values, (3) robust – both from a technical perspective while taking into account its social environment*” (European Commission, 2019). The Guidelines proposed seven essential requirements that AI systems must achieve to be considered trustworthy: “(1) human agency and oversight, (2) technical robustness and safety, (3) privacy and data governance, (4) transparency, (5) diversity, non-discrimination and fairness, (6) societal and environmental well-being, (7) accountability” (European Commission and AI HLEG, 2019).

In February 2020, European Commission released a *White Paper on AI: a European approach to excellence and trust*, which aims to define AI, underly its benefits and technological advances in areas such as medicine and security, and sketch its potential risks: discrimination, gender inequality, privacy and transparency issues (European Commission, 2020). The Ethics Guideline contains a chapter Assessment List for Trustworthy AI (ALTAI) that was presented in its final version in July 2020 as a stand-alone document. The purpose ALTAI is to provide a self-evaluation guideline for flexible usage by stakeholders among which AI HLEG exemplifies “*AI designers and AI developers of the AI*

system; data scientists; procurement officers or specialists; front-end staff that will use or work with the AI system; legal/compliance officers; management.” (European Commission and AI HLEG, 2020).

In April 2021, the European Commission forwarded the first legal framework on AI aiming at the four levels of risks of AI: unacceptable risk, high risk, low or minimal risk (European Commission, 2021), and by the end of September 2022, an AI liability was proposed. In 2023, European Center for Algorithmic Transparency (ECAT) was initiated to secure compliance and transparency of AI systems enforcing the Digital Services Act (DSA), (European Commission, 2023). On July 12, 2024, the EU AI Act was released in the EU’s Official Journal, being the first comprehensive legal framework in regulating AI worldwide, and it deploys AI risks (unacceptable risk, high-risk, limited risk and minimal risk), describing General Purpose AI (GPAI) and exploits prohibited AI systems, focusing on vulnerabilities, manipulative techniques, biometric systems risks (EU AI Act, 2024).

3. Applications of Artificial Intelligence

In medical practice, massive amounts of data are generated, such as images (magnetic resonance imaging – MRI, computed tomography – CT, radiography), time series signals (electroencephalography – EEG, electromyography – EMG, electrocardiography – ECG), audio (speech), and text documents (medical reports), (Kavasadis *et al.*, 2023). The application of AI in medicine generates concerns that it would replace medical practitioners and human decision-making. However, AI is regarded as a support tool to assist the judgment of doctors and enhance diagnosis and clinical treatment. Present-day use of AI in medicine includes applications such as diagnosis and prediction-based diagnosis, clinical care, drug development, management and planning in the healthcare system, and public health surveillance (WHO, 2021). Additionally, there are already AI health applications in clinical use in Europe, showing great results in the areas of diagnostics and medical imaging analysis.

The first example is *Ada*, an AI health app that, based on the assessed symptoms, offers medical guidance to the person. It is CE-marked (class IIa) by EU-MDR according to regulation (EU) 2017/745 (EU-MDR), it complies with EU-GDPR, and it is certified with the quality standard for information security (ISO 27001) and quality management (ISO 13485), (Ada Health GmbH, 2023). The application was named after Ada Lovelace, the first computer programmer that computed a sequence of numbers using the Analytical Engine (Encyclopaedia Britannica, 2023). *Ada* was developed by a team of an entrepreneur, a neuroscientist, and an NHS doctor and it currently has 13 million users and is accomplished to assess 30 million symptoms (Ada Health GmbH, 2023).

With the use of *Ultromics' EchoGo Heart Failure*, a cloud-based Software-as-a-Service, practitioners may automate the prediction of coronary

artery disease with more precision, safety, accessibility, and affordability. The application was developed by a team from the University of Oxford and Mayo Clinic in the United Kingdom and it is FDA-approved, ISO 27001, and ISO 13485 certified (Ultromics, 2023). Another example from cardiology is *Corti*, a Danish voice-based AI that detects out-of-hospital cardiac arrest during emergency calls by analysing features such as the tone of voice and breathing patterns (Corti, 2023).

Rayscape, based in Timisoara, Romania, shows great promise in radiology diagnosis using CXR technology to detect pathologies on chest X-rays, localize lesions, prioritize patients based on pathology, generate SARS-Cov2 score; and lung CT for lung cancer detection (Rayscape, 2023).

MediNav is a software developed by a Romanian team and it focuses on report writing and form filling helping doctors during their consultations and saving time spent on medical reports aiming for faster result delivery. Its main focus is on radiology, ultrasonography, and anatomopathological (MediNav, 2021).

4. Challenges, risks and ethics principles to regulate AI in medicine

With the advance growing and integration of AI technology in the healthcare sector, ethical consideration should be taken into account to learn the current state, potential and limitations of using AI in clinical practice, in addition, to understand the risks and limitations awareness when implementing and using AI solutions.

In 2021, the World Health Organization published guidance on “Ethics & Governance of Artificial Intelligence for Health” which describes applications of AI for health; laws, policies, and principles of AI usage for health; ethical principles and challenges of AI in healthcare; how to build an ethical approach to use AI in healthcare; liability regimes for AI in health; and elements of a framework for the governance of AI for healthcare (World Health Organization, 2021). This guidance lists six ethical principles identified by WHO Expert Group as most appropriate for the creation and application of AI technology for health: (1) protect autonomy; (2) promote human well-being, human safety and public interest; (3) ensure transparency, explainability and intelligibility; (4) foster responsibility and accountability; (5) ensure inclusiveness and equity; (6) promote artificial intelligence that is responsive and sustainable.

The application of AI in clinical healthcare practice has enormous potential to improve it, as the previous section suggested, but it also poses ethical issues and challenges that conflict with the previously enumerated principles that we now examine. In the second chapter of *AI in clinical medicine. A Practical guide for healthcare professionals* (Barkal et al., 2023) a general framework can be described introducing:

- Legal constraints
 - accountability and responsibility
 - transparency and explainability
 - interpretability
 - liability
- Governance and oversight
 - ethical committees
 - regulatory frameworks
 - quality control
- Equity and patient-centered care
 - bias and fairness
 - informed consent
 - autonomy
- Data privacy and security
 - General Data Protection Regulation (GDPR) (EU)
 - cybersecurity
 - federated learning
- Education on AI
 - training
 - interdisciplinary practitioners collaborations

Privacy and data protection, or confidentiality, of the patient, are some of the main issues encountered by developers and users of AI since it requires big datasets. To address this issue, legal consent should be acquired before using the data. To account for the potential of big data various consent models have been created along the traditional one, because it is difficult to forecast how patient data will be used and if the patients will consent for unknown reasons (Savulescu *et al.*, 2024). In a recent paper, the following types of consent have been delved into: broad consent, a wide range of consent of the individual of specified uses; meta-consent, individuals consent to the type of use of data; and dynamic consent, personalised consent of the individual (Savulescu *et al.*, 2024).

According to General Data Protection Regulation (GDPR), all personal data of the patient is protected to avoid discriminative decisions based on individuals' personal information. To meet the GDPR regulations, Federated Learning, decentralized collaborative learning, is being proposed as a potential yet demanding solution (Truong *et al.*, 2021). The purpose of AI is to analyse the patient's medical data and improve and fasten the diagnosis, especially in oncological imaging, decreasing the patients' waiting time (Baumgartner *et al.*, 2023). By identifying possible bias cases, generalizable AI, on condition to improve lives by building fair AI models, we must direct our gaze at prior events when models discriminated against individuals based on their social and ethnic backgrounds (Ueda *et al.*, 2024; Ferrara, 2023). Ueda *et al.* (2024) and Ferrara (2023) highlight in their papers that AI bias can derive from the dataset, AI

systems design, and human-bases bias, especially clinician-AI bias, and patient-A bias, the final pair rises from varying levels of trust and understanding of AI. Behavioural data surplus (WHO, 2021) represents a major concern when collecting patient data with the help of technology, the exceeded data should not be repurposed by sharing it with other entities. When collecting human data to train a model, it takes only a second to leak the information of the patients, an issue that puts them in danger. The integration of AI technologies in the medical system, very interconnected nowadays, emerges with Cyber threats. A study conducted by Alanazi displays a few threats to medical systems that do not integrate Cybersecurity: sensitive medical data leaks, the safety of the patient, cyber-attacks, and financial and legal penalties for the hospital (Alanazi, 2023).

Another important item when creating an ethical AI represents the model card, which is its short and transparent documentation. Communicating the key information to people, how the model has been trained, on what datasets, and what is the main purpose of using it on a patient increases awareness and people will overcome rigidity. Explainable artificial intelligence (XAI) is a useful tool for addressing growing ethical and legal issues as well as important How? and Why? questions concerning reliable AI systems. The 4th, 9th, and 10th chapters of the book *The AI Revolution in Medicine: GPT-4 and Beyond* focuses on this matter, discussing the importance of educating the public on understanding AI limitations (Lee *et al.*, 2023). However, one challenge that XAI research faces is the lack of agreement on the meanings of the key concepts. In often academic circumstances, the use of words explainability and interpretability are interchangeable, whereas explainability refers to explanations given beforehand, the ability to describe why an AI model made a decision, and interpretability is related to the explanations given after hand (Barredo Arrieta *et al.*, 2020; Rudin, 2019), how easily a human being can understand the decision-making process of an AI model.

With the growth of AI in medicine, informed consent and autonomy have also expanded (Gerke *et al.*, 2020). Patients have a right to information regarding their diagnosis, condition, treatment, results, costs, risks, health insurance and other medical information (Farhud and Zokaei, 2021).

As promising AI might seem in the healthcare sector, empathy during medical consultations seems difficult to overcome as an AI. The healing process of the patients comes along with the empathy and sympathy of the medical practitioners creating a “human-human” relationship, which may not be achieved by robots, especially in the psychiatric area (Farhud and Zokaei, 2021).

5. Conclusions

Despite the wonderful advances of AI in medicine and healthcare and its great potential, we need to shift our focus from the qualities usually considered while making machines such as computational power, accuracy, and scalability

to ethical and regulatory challenges, features namely explainability, fairness, robustness, transparency, and privacy. Additionally, it is important to promote participation from a variety of groups in debating and evaluating the dangers and societal ramifications of AI and to improve global collaboration and communication to cooperatively handle such issues.

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CONSIDERAȚII ETICE PRIVIND ADOPTAREA ALGORITMILOR DE INTELIGENȚĂ ARTIFICIALĂ ÎN MEDICINĂ

(Rezumat)

Un sistem de asistență medicală mai rapid și mai inteligent, care utilizează metode de inteligență artificială (IA), ar putea detecta în mod robust bolile critice, reducând perioada de așteptare a pacienților pentru diagnostic și tratament. În cazul utilizării unor astfel de instrumente, au fost ridicate în mod constant probleme etice legate de protejarea vieții private. Modelele nediscriminatorii de inteligență artificială ar trebui să evite orice posibilă sursă de favorizare în seturile de date studiate, fără să țină cont de criterii de rasă, sex, religie și alte categorii. Mai precis, Comisia Europeană și Organizația Mondială a Sănătății au generat un set de proceduri prin care se solicită părților interesate

de IA să depășească aceste provocări în domeniul medical. Transparența cu privire la procedurile și echipamentele de achiziție a datelor, informațiile detaliate despre modul în care modelul a fost antrenat și evaluat și eforturile extinse în direcția explicării modului în care au fost generate deciziile modelelor sunt esențiale pentru ca pacienții să accepte aceste tehnologii. Lucrarea analizează provocările adoptării inteligenței artificiale în domeniul medical, concentrându-se atât pe oportunități, precum diagnoză și acuratețe îmbunătățită, tratamente personalizate, monitorizare la distanță, cât și pe limitările și riscurile asociate, confidențialitatea și securitatea datelor, răspundere și responsabilitate.