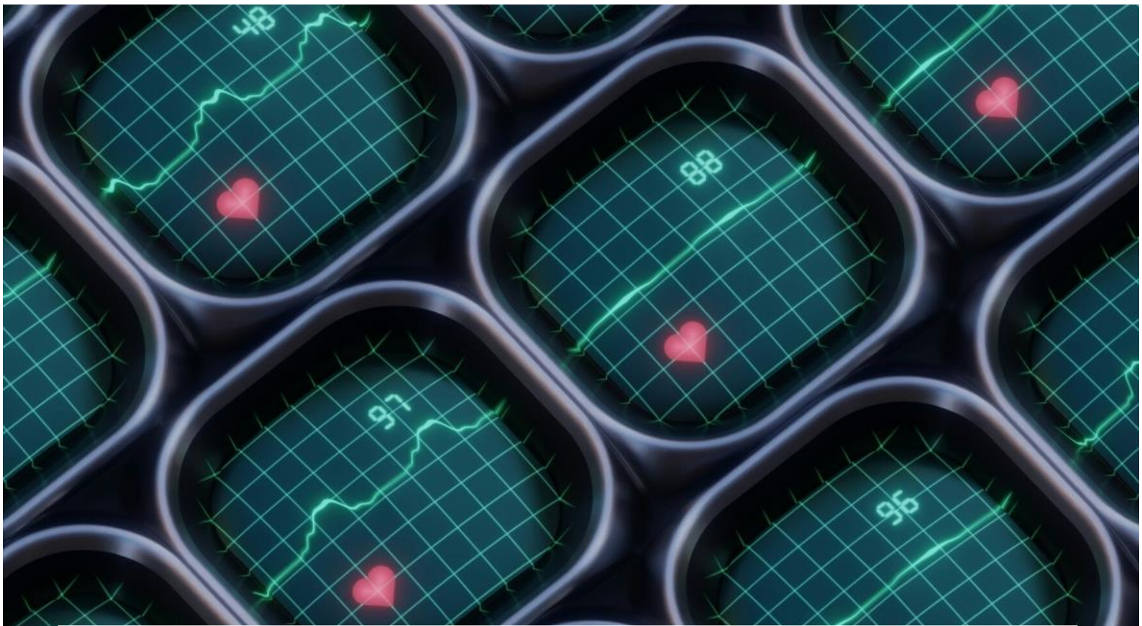
Corasaniti G, 'Digital bioethics... Next step forward? ' (2024) 2 EJPLT, 10 – 17.
DOI: https://doi.org/10.57230/EJPLT242GC

EJPLT
ISSN 2704-8012



Digital bioethics... Next step forward?

Bioetica digitale... Il prossimo passo in avanti?

Giuseppe Corasaniti
Full Professor of Philosophy of Digital Law
Universitas Mercatorum
Full Professor of Artificial Intelligence and Law
LUISS Guido Carli

Abstract

The integration of artificial intelligence (AI) in healthcare raises ethical and legal challenges, requiring a strong regulatory framework. The WHO emphasises autonomy, transparency and accountability in the use of AI, while the EU regulation classifies medical AI as high-risk, imposing compliance and data protection obligations. Liability remains a key issue due to AI's opaque decision-making processes. Digital bioethics highlights the need for interdisciplinary collaboration to ensure equitable access, mitigate bias, and balance technological advances with patient rights and legal responsibilities. A holistic approach is essential for the ethical integration of AI in medicine.

L'integrazione dell'intelligenza artificiale (IA) nell'assistenza sanitaria solleva sfide etiche e legali, richiedendo un solido quadro normativo. L'OMS pone l'accento sull'autonomia, la trasparenza e la responsabilità nell'uso dell'IA, mentre il regolamento dell'UE classifica l'IA medica come ad alto rischio, imponendo obblighi di conformità e protezione dei dati. La responsabilità rimane una questione fondamentale a causa dell'opacità dei processi decisionali dell'IA. La bioetica digitale evidenzia la necessità di una collaborazione interdisciplinare per garantire un accesso equo, attenuare i pregiudizi e bilanciare i progressi tecnologici con i diritti dei pazienti e le responsabilità legali. Un approccio olistico è essenziale per l'integrazione etica dell'IA in medicina.

Keywords: AI; Healthcare; Digital Bioetchics

1. Introduction.

The World Health Organization (WHO) has published guidance on the ethical use of artificial intelligence (AI) in healthcare. According to the WHO, AI holds great promise for improving healthcare worldwide if ethics and human rights are at the heart of its design, implementation, and use. To regulate and govern AI, the WHO has published new guidance that provides six principles for limiting risks and maximizing the inherent opportunities of AI for health. These principles are essentially indicated in the need to protect the autonomy of operators, in the promotion of people's safety and well-being, but also in the promotion of transparency and responsibility through ethically correct and transparent choices through reactive and sustainable tools. The report also highlights that opportunities are linked to challenges and risks, including the unethical collection and use of health data; encoded biases in algorithms and AI risks for patient safety, cybersecurity and the environment. By following these underlying principles and addressing these general issues, we can understand that ensuring the ethical use of AI in healthcare. In the hospital environment, it means stimulating the responsible use of machinery and diagnostic software that replace the professional operator, and it is increasingly common for artificial intelligence systems to intervene in the treatment process both in the diagnostic and therapeutic phases, allowing the healthcare worker to reach more certain and precise diagnoses and more effective and less invasive surgical therapies.

2. Regulatory Framework for AI in Healthcare.

The upcoming European regulation on artificial intelligence specifically addresses the issue of medical and health applications in different ways, depending on the level of risk they pose. In general, the proposed regulation sets out requirements and obligations for developers, providers and users of artificial intelligence systems operating in the EU, in order to ensure security, transparency, traceability, non-discrimination and respect for the privacy and fundamental rights of individuals.

In particular, medical and health applications are considered high-risk if they fall into one of the following categories such as medical devices or health products that are or incorporate artificial intelligence systems, such as those used for the diagnosis, prognosis, monitoring or treatment of physical or mental diseases or conditions, intelligent systems that provide essential social services, such as those used for remote healthcare, medical emergency management or care for the elderly or disabled and those that are then used for remote biometric identification, such as those used for facial or fingerprint recognition.

For these high-risk applications, the proposed regulation provides that: Artificial intelligence systems are subject to a conformity assessment before being placed on the market or put into service, in order to verify compliance with the requirements of the regulation and are provided with clear and complete information on their characteristics, functionality and limitations, as well as instructions for their correct and ethical use.

They will have to be equipped with specific tools to ensure the quality and security of the data used for their learning and operation, as well as to prevent or mitigate the risks of bias or discrimination. In addition, they will in any case have to ensure the traceability and documentation of their operations and their results, as well as to facilitate human control and human intervention in case of need and respect for the privacy and protection of the personal health data of users and those affected by their decisions or actions. Finally, providers and users of AI systems register their systems in a European AI database, in order to facilitate monitoring and supervision by competent authorities.

3. Liability and Ethical Considerations in AI-driven Healthcare.

Even in the absence of a precise regulatory discipline, the risk of easily incurring civil or criminal liability is evident for the health care provider. One of the main problems already addressed is the very nature of the tool, which sometimes does not allow the operator to access the processes through which the desired result is achieved. And this profile is extremely delicate if and to the extent that the system has been provided with adequate operating instructions and if and to the extent that these instructions have been complete and subject to adequate training at the health and internal level.

This system has already been problematically defined by legal doctrine, noting that it is not always possible for man and in particular for the operator of a health profession to know and verify the logical process and the motivation of the machine's choices. When considering the civil liability of the doctor and the hospital, this means that the non-contractual liability of the doctor, as it is currently regulated by law, would require the injured party to provide almost difficult evidence to obtain compensation for damage to health caused by the doctor using AI tools, due to the opaque nature of the tool used by the doctor, which does not allow an easy identification of a causal link between fact and damage. The use of artificial intelligence in health services allows the doctor to monitor and confirm the outcome produced by the program. This is because the doctor is tasked with guiding the algorithm in real-time and because there is an opportunity to review the software's output. This moment of verification allows the doctor to correct any errors before the treatment is administered to the patient.

When software works with a high level of autonomy, intervening directly on the patient for diagnostic or therapeutic purposes, the question of liability becomes more complex. This is especially true for software that, due to its design and development, does not allow you to clearly understand how it works.

In such circumstances, it is important to determine whether the physician can be held liable for the damage caused by the algorithm, even if he or she does not have the real possibility of influencing or correcting the actions of the software. In fact, possible malfunctions and related damage to patients cannot be ruled out, especially since artificial intelligence systems, especially generative ones, are subject to evolutions, updates and changes that affect their operation, often in an unpredictable way for developers.

In addition, it is crucial to consider that the continuous evolution of artificial intelligence could lead to future scenarios in which the software could make independent and even original and innovative clinical decisions in the solution of the clinical or surgical problem. In these cases, the question of responsibility becomes even more critical. New regulatory frameworks may need to be developed to address these emerging challenges and ensure patient safety.

The evidentiary aspect, however, does not appear to be so decisive if the same principle of reversal of the burden of proof were to be adopted for the regulation of artificial intelligence as is currently provided for in the processing of personal data, on the basis of the perspectives gained at European level. In any case, there are still margins of irresponsibility for robots and in any case for algorithmic solutions embedded in the hardware, which then means that the social cost of the damage could eventually fall on the injured party. There is still no shortage of analyses aimed at the preliminary identification of viable legal solutions is considered of considerable urgency if we think of the growth and spread of the use of AI systems in recent years, in all sectors and in particular in the health sector, and if it is assumed that an increase in the use of the medium even in the short term will lead, in the short term, an inevitable increase in the chances that a harmful event will result from the use of the vehicle. It is not possible to conceive regulatory and ethical solutions except in an interdisciplinary key to ensure a balanced and equitable development of smart technologies in health Already in a 2017 Resolution, the European Parliament hypothesizes the alternative introduction of an objective liability regime or a risk management approach, which makes it possible to verify which is the subject who "is able to minimize the risks and deal with the negative impact".

Solutions that, according to some, are not to be envisaged as alternatives, but rather as reconcilable with each other, both forfeitable in a system of protection that works in a uniform manner.

And in fact, it is certain that the choice of an objective protection system does not in any way exclude, and indeed in some ways suggests, the possibility of providing rules aimed at risk management by subjects operating along the production chain. But who could be responsible for mistakes or malicious decisions made by AI systems? How to define a concept of responsibility in every case in which the diagnostic or therapeutic decision is taken by an algorithm?

In principle, a responsibility can be defined from the point of view of the design of the system or the incorrect setting of the criteria of its operation, but much more complex appears to be the issue that refers to the synchronization of data, the adequate training and training of the personnel in charge, the adequate understanding of what is the operational functioning of the artificial intelligence system provided on the basis of precise or imprecise settings, which could clearly be an element that can be evaluated differently depending on the contexts and characters of the system itself.

A first problem concerns in particular what is the training of the data and the verification of the completeness and correctness of the datasets themselves. In fact, there has been the possibility that AI in all fields of its application perpetuates or amplifies existing discriminations. Hence the need to address bias in training. In fact, algorithms often operate as real "black boxes", difficult to control and also difficult to reconstruct in options as well as in acquisitions from structured datasets, but the transparency of decision-making methods should also be highlighted according to criteria that are always transparent and explainable. The need to structure the specific sector regulations in the health and pharmaceutical sectors also emerges in the health sector.

Many software can be classified as medical devices according to Regulation (EU) 2017/745, but this regulation does not provide indications on liability, limiting itself to providing for a general liability of the manufacturer in any possible case of malfunctions and damages resulting from the same, with the attached obligation to ensure sufficient financial coverage in relation to this liability, typically in the form of insurance. Furthermore, it is quite evident that a very delicate evidentiary issue is specifically framed for the injured party, who may not be able to demonstrate not only a malfunction of the apparatus but also its functional non-compliance with the adequate resolution deriving from an incorrect reference data context.

4. Digital Bioethics and the Ethical Use of AI in Healthcare.

A digital "bioethics" is therefore envisaged in which, beyond the priority evaluations of a moral order, the criteria can be precisely verified in a synergistic and interactive key through feedback and information strategies not limited to the traditional fields of medical sciences, but extended in the professional comparison and in the cognitive contribution of other categories involved to encourage an increasingly careful use of digital tools. Digital bioethics can therefore be defined as an emerging discipline that deals with the ethical issues raised by the use of digital technologies in the field of health, life and society.

The issue of digital bioethics is then divided into several aspects that can be variously explored, including first of all the effective protection of the personal and sensitive data of patients and citizens, which can be collected, processed and shared by digital devices, applications and platforms, often without their informed consent or with the risk of privacy and security violations. In addition, in general, from a health point of view, the issue of equitable and universal access to digital health resources and services arises, which can offer opportunities for prevention, diagnosis, treatment and monitoring, but also create disparities and discrimination between those who have them and those who are excluded or marginalized. The same varied responsibility and transparency of algorithms and artificial intelligence presents controversial aspects that can influence clinical decisions, health policies and the behavior of those involved in the health system, but also generate errors, biases and biases that can compromise the quality and effectiveness of care and the protection of patients' rights. There is general agreement on the issue of safeguarding the dignity and autonomy of people, who may be subjected to forms of surveillance, manipulation or coercion by public or private actors who use digital technologies to control, influence or modify their choices, values and identities.

Digital bioethics therefore increasingly requires a multidisciplinary and participatory approach, involving all interested stakeholders (health professionals, researchers, developers, regulators, patients, citizens) in dialogue, reflection and the definition of principles, norms and good practices for an ethical, responsible and sustainable use of digital technologies in the field of health, life and society. It should be based on a multidisciplinary and participatory approach, involving experts from different areas of knowledge, stakeholders, users and citizens.

Therefore, digital bioethics must overcome an individualistic view and focus on the interconnections and interdependencies between humans and technology. This requires an interdisciplinary approach involving different skills to address the ethical challenges posed by the use of algorithms, big data and artificial intelligence in the medical and healthcare fields. Only through a broad and shared ethical reflection accessible to all, classical bioethics will be able to evolve and will be able to give a meaning and a valuable orientation to techno-scientific progress, avoiding its "dehumanization".

5. Conclusions.

New issues are envisaged such as the essentiality of treatments in relation to their cost in terms of access to intelligent technologies, and the traditional responsibility of the professional seems to have to be extended in many cases in the consideration of the understanding of the different techniques of interpretation of the available data, of the opportunity to know how to read and interpret diagnostic data in the light of what is expected to be the best technology in relation to the case diagnostic test in the light of a medium interpretation as well as in consideration of the resources available to the health facility concerned.

It is no longer possible to conceive of a role of ethics understood in an integrative sense, having instead to conceive of a growing integration between different experiences, each oriented towards the well-being and recovery of the patient but at the same time each one that can be connected to the best available technology, to the ability to connect and compare with the outside world for the health facility in order to verify not only the possible options but above all in a collective way to reconnect the picture information available in an increasingly globalized context.

The same organization, typical of traditional bioethics committees, which are mostly based on a comparison of experiences, each understood in its separateness, could require an adjustment in the sense of expanding digital sensitivity and informed attention to emerging technologies. Today more than ever in the context of healthcare facilities it is necessary to proceed with the articulation of a coordinated series of controls that are oriented in a sensitive and innovative way towards a dimension of recovery and well-being that cannot fail to be considered except in the digital sphere. All this does not integrate only one problem but rather describes a growing series of adaptive problems that concern both strictly and traditionally legal issues as well as the need to understand as soon as possible through technologies what is the best choice in terms of effective protection of citizens' right to health and at the same time the meaning and overall orientation of the information available in terms of therapy and therapeutic intervention through the best technologies.

All this requires a constant exchange of information between public and private, a consideration and classification of data and aggregation of data in homogeneous terms and is in some way organic with respect to what is the main function of health facilities. In my opinion, it is necessary to maintain an open and above all sensitive vision, capable of being able to read what the data express in their direct incidence in statistical terms but above all what the data do not express, that is, what is usually traced back to the onset of pathologies applied not considered and to forms of therapy and diagnosis, even of an experimental nature, based on the correct way of associating emerging patterns of a specialized nature, all the more so in a context globalized.

The challenges that await the law of medical sciences can be understood and interpreted through a continuous comparison, a sensitivity and a constant openness to technological knowledge that is not only an uncritical use, but contrary to the use of the human being. thus improving their condition as well as their expectations of well-being and recovery.

A first problematic aspect is represented by the need to ensure an integrated and complementary vision in bioethical terms, and this passes through an integrated and complementary vision of the available technologies, a careful reading of the data and alternatives that can be traced and defined in terms of treatment and medical intervention, this passes through a new organization of the competences usually associated with bioethics committees, in which knowledge does not intersect, but in some way remains separate, defining only an optimal conception following a central point of view which is the health one, indeed mostly the one specialized in medical terms, without sometimes glimpsing the usefulness of a comparative method or an applicative vision of the technology available and usable in the concrete scenario. Just as it was decided not to leave doctors alone in the crucial choices relating to health management and the optimal organization of services, today it seems essential to understand how technologies can simplify and integrate the communication framework but also define new protocols and therapeutic systems through a constant, open discussion defined in an open sharing action that can be linked to different areas and evolutionary scenarios that were previously unrelated to the past.

Digital technologies integrate and integrate with each other and require a sensitive, conscious and aware vision of what are the possible areas of risk, but equally capable of asking questions about the methods generally practiced and of following new and original paths never considered, in a constant research that knows how to understand and define new possible paths[i].

[i] T Magnin, P. Giorgini, 'Digital Driven Technosciences: Epistemological and Ethical Questioning' (2022) 1 Etica & politica - Ethics & politics, 379; G Di Rosa, 'Quali regole per i sistemi automatizzati "intelligenti"?' (2021) 5 Rivista di diritto civile, 823; L Palazzani, 'Clinical trials in the time of a pandemic: implications for informed consent' (2021) 2s BioLaw Journal - Rivista di BioDiritto, 35; C Botrugno, 'Innovazione tecnologica in salute e "commodification". Verso un nuovo dovere di protezione dell'individuo?' (2020) 1 Jura Gentium, 140; G Fioriglio, *Informatica medica e diritto. Un'introduzione* (Mucchi Editore 2020); A D'Aloia, 'Il diritto verso "il mondo nuovo". Le sfide dell'Intelligenza Artificiale' (2019) 1 BioLaw Journal - Rivista di BioDiritto, 1; EA Ferioli, 'L'intelligenza artificiale nei servizi sociali e sanitari: una nuova sfida al ruolo delle istituzioni pubbliche nel "welfare" italiano' (2019) 1 BioLaw Journal - Rivista di BioDiritto, 10; L Marilotti, 'Ipotesi per una gestione partecipata delle biobanche genetiche concepite come beni comuni' (2023) 2 BioLaw Journal - Rivista di BioDiritto, 383; G Fioriglio, 'Intelligenza artificiale e medicina: alcune riflessioni sui profili giuridici ed etici' (2021) 143 Notizie di Politeia, 162-166; MD Garasic, 'Informed consent, clinical research, covid-19 and contact tracing apps: some neuroethical concerns' (2021) 2s BioLaw Journal - Rivista di BioDiritto, 85; A Santosuosso, 'About coevolution of humans and intelligent machines: Preliminary notes' (2021) 1s BioLaw Journal - Rivista di BioDiritto, 445; A Monreale, 'Rischi etico-legali dell'Intelligenza Artificiale' (2020) 3 DPCE online, 3391; FG Pizzetti, 'La Costituzione e l'uso in sede giudiziaria delle neuroscienze (e dell'intelligenza artificiale): spunti di riflessione' (2019) 2s BioLaw Journal - Rivista di BioDiritto, 697; C Casonato, 'Costituzione e intelligenza artificiale: un'agenda per il prossimo futuro' (2019) 2s BioLaw Journal - Rivista di BioDiritto, 711; D Amoroso, G Tamburrini, 'I sistemi robotici ad autonomia crescente tra etica e diritto: quale ruolo per il controllo umano?' (2019) 1 BioLaw Journal - Rivista di BioDiritto, 2; S Marchiori, P Sommaggio, 'Break the chains: a new way to consider machine's moral problems' (2018) 3 BioLaw Journal - Rivista di BioDiritto, 15; A Bertolini, 'Human-Robot Interaction and Deception' (2018) 2 Osservatorio del diritto civile e commerciale, 645; N Busto, 'Carta europea sulla robotica: una proposta di "roboethics" per le "self-driving car"' (2017) 2 Ciberspazio e Diritto, 289; EM Biganzoli, B Cesara, 'La figura del biostatistico nei Comitati Etici (CE). Linee guida per il ruolo del biostatistico e per l'attività del biostatistico nella revisione dei protocolli degli studi proposti al parere dei CE' (2016) 5 Medicina e morale, 567; C Salazar, 'Umano, troppo umano…o no? Robot, androidi e cyborg nel "mondo del diritto" (prime notazioni)' (2014) 1 BioLaw Journal - Rivista di BioDiritto, 12; L Caenazzo, D Rodriguez, P Tozzo, 'Aspetti etici e tutela dei minori nella gestione delle biobanche a scopo di ricerca e forense in Italia' (2011) 2-3 Zacchia, 237; A Marturano, 'Biologi molecolari: hacker di dati umani? Bioetica e proprietà intellettuale nella ricerca bioinformatica' (2006) 4 Medicina e morale, 741.