Reconfiguring informed consent in the age of artificial intelligence: Bioethical and normative challenges in digital health

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Abstract

Man knows that his time to live is limited. Anxiety and the desire to eliminate limited time from your life has been a constant throughout human history. Current advances in biotechnology, namely and especially Artificial Intelligence, "seem to lead" man towards his desire for immortality. This article starts from an anthropological narrative in confrontation with a technological narrative, having as a question for reflection: "What makes us human?" Given the exponential development of Artificial Intelligence with an impact on human life and people's health, we reflect on the challenges of Artificial Intelligence and the opportunities or threats, as well as the associated ethical issues, informed consent, not in relation to values humans, but in relation to new rights and new duties.

Keywords: Anthropology; Artificial Intelligence; Duties; Ethics; Informed Consent; Rights.

"I am a man, so nothing that is human can be considered as alien to me."
(cf. Terence).

1. Introduction

Heidegger (2023), in his *Letter on Humanism*, states that Humanism can be summarized as follows: "to reflect so that man may be human and not inhuman, barbaric outside of his essence" (Martin, 1998).

In short, humanists are those who dedicate themselves to the study and action of this astonishing complexity that is a human being in its essence, traveling from its ontology to its ethical structuring.

Our conception of man, from the perspective of biological ontology, typically stages nine months, sheltered in the mother's body, and then emerges into the world, beginning a developmental process that manifests in the time he is given to live, until death. This development, in the human being, grants him a special ontological category.

From his biological constitution, the human brain has a certain area, with a few million neurons, that make all the difference: the executive brain (Goldberg, 2015), which is almost like the conductor of a large brain orchestra, regulating the activation of groups of neurons and their multiple synaptic networks so that human decisions are a coherent symphony rich in meaning, both rational and emotional. It is through this that the human being elaborates and models his decisions. As Daniel Serrão states, man is essentially a being of desires and decisions, who imagines and plans the future, knowing that his time as a human being is limited.

Conscious of this reality, the man who knows his time to live is limited, the anxiety and desire to eliminate the limited time of his life have been constants throughout human history.

Current advancements in biotechnology, particularly Artificial Intelligence (AI) and Human Genome Editing, "seem to lead" man toward his yearning for immortality and a world dominated by technology applied to digital health. The application of AI in the context of health calls into question, on one hand, the fundamental rights of the individual subjected to digital intervention, and, on the other hand, raises the assumption of new duties for

healthcare professionals who use AI as a tool in their professional activity, namely in teleconsultation, telemedicine, and telesurgery.

To understand what makes us human, we begin with an anthropological reflection and the ethical issues associated with it, particularly about the principles and values that should guide AI—in both its threats and opportunities. Finally, informed consent, as a fundamental right, involves not so much a reflection on ethical values, but rather on new rights and new duties.

In recent years, scholarly discourse has increasingly addressed the ethical and legal implications of Artificial Intelligence (AI) in healthcare, focusing on informed consent, patient autonomy, and algorithmic transparency. Floridi et al. (2018) proposed an ethical governance framework that highlights the need for explainability in AI-driven clinical decision-making. In parallel, Vayena et al. (2018) argued for the reinterpretation of informed consent in the context of predictive and personalized medicine. Mittelstadt et al. (2016) emphasized the risks of bias, opacity, and limited accountability inherent in algorithmic systems, calling for enhanced ethical safeguards and the reinforcement of patient rights. As Floridi and Cowls (2019) further contend, AI's opaque and autonomous decision-making capabilities fundamentally challenge traditional bioethical paradigms, necessitating a recalibration of normative frameworks to accommodate these emergent complexities.

2. Methodological Approach

This study adopts a normative-theoretical methodology, grounded in a critical analysis of selected scholarly literature, international legal frameworks, and emblematic case studies involving the use of AI in healthcare. The analytical process comprises three steps:

(i) identifying key bioethical principles (autonomy, beneficence, non-maleficence, justice); (ii) examining how these principles are challenged or reconfigured in contemporary digital health practices; and (iii) applying these principles to real-world cases through ethical reasoning.

The method is deductive and interpretative, drawing on doctrinal and legal sources to offer a conceptual and normative contribution to the debate on informed consent in AI-mediated contexts.

To support the ethical reasoning process, the following analytical matrix contrasts traditional medical ethics with emerging tensions in AI-driven healthcare:

Table 1: Ethical tensions in classical vs. AI-mediated informed consent.

Principle	Classical Medicine	AI-Mediated Healthcare
Autonomy	Patient chooses based on human explanation	Patient relies on algorithmic output, often opaque
Beneficence	Physician judges best interest	Algorithm optimizes outcomes statistically
Accountability	Physician is liable	Shared liability between human and technological agents
Transparency	Human reasoning is explicit	AI decision-making may be non-interpretable or black-boxed

This typology illustrates the layered complexity introduced by algorithmic systems and reinforces the need to reconceptualize ethical duties and legal safeguards in the age of digital healthcare.

While this study does not adopt an empirical design, its normative-theoretical approach adheres to established protocols in applied ethics. Normative analysis is widely recognized as a valid scientific method in bioethics, as

it allows for the conceptual refinement of principles and the interpretive assessment of moral dilemmas within specific technological contexts (DeGrazia & Beauchamp, 2019; Gracia & Júdez, 2004). Through a structured engagement with primary ethical principles—namely autonomy, beneficence, non-maleficence, and justice—the study advances critical reflection on their applicability in AI-mediated healthcare. This method does not aim to produce statistical generalizations but to offer conceptual clarity and ethical guidance for policy-making and clinical practice.

3. Brief Anthropological Narrative

3.1. The Narrative of the Beginning:

In the narrative of the beginning, from Genesis (Couto, 2013), "sexual polarity is a created reality, not divine" (Von Rad, 1972). In truth, the Bible does not know "man" except as man and woman. The biblical narrative recognizes humanity only as it has always perceived itself: two complementary and reciprocal beings, whose attraction, needs, and possibilities of union are inscribed in their own conformation (Couto, 2013).

In the biblical account, when God pronounces that emphatic "it is not good for man to be alone" (Gn 2:18), He alerts us to the grave problem of solitude, which consists of man potentially being left alone amid objects. This alert leads us to think that when man surrounds himself with objects, he aims to become the owner of everything and everyone. Surrounded by objects, man tends to lose his humanity.

Still, in this biblical context, as Adolphe Gesché rightly asks: "Does the mysterious plural—let us make—no longer contain our presence?" (Gesché, 1991). Yes, in fact, this "let us make" means that God does not speak only to Himself but also to man, inviting him to join in the work of creation (Wénin, 1998), in the sense of the duty to dominate the earth and subdue the earth and its creatures (Gn 1:26b-28b). Clearly, this is not about a domineering rule of man but about becoming a collaborator, a co-creator, and being in the world as God is in Heaven, receiving the world and the earth as a gift, knowing how to give it back to God, freely.

It is also, as Paul Beauchamp points out, about governing with sweetness, a sweetness that does not limit man's power, for it is Power itself (Beauchamp, n.d.). This means that the biblical verb "to dominate" and "to subdue" imply leading, commanding, either to protect and defend the house of life, or to resist injustice and the animality that might subjugate man.

That majestic plural "let us make" spoken by God does not exist in biblical anthropology (in Hebrew), rather, it is a deliberative or declarative plural given the importance of the work of creation. However, man did not, and often still does not, know how to interpret this "let us make." Man wanted, and still wants, to dominate instead of caring, and thus he does not know how to dominate the animal within him. Dominated by his animality, he was soon expelled from the garden where God had placed him.

Man quickly concluded that he wanted to dominate other men, and thus was expelled from the "garden of delights..."; this desire for domination leads him to kill his neighbor. It has been this way since his origins: in man lies the yearning and desire for possession and power. Yet, never before has man, in his quest to dominate a world that welcomed him freely, been so close to being expelled from his humanity.

Man, created by love and given to himself by love; the world created by love, given to man by love—this is the meaning, reason, and intentionality of the work of creation. To read man and to read the world without respecting the creator's intentionality, who gave it to us, selfishly interrupts the sense of humanity's creation, and by not respecting this sense of God, man lives according to his own interests and whims.

Man is not the owner but the gift. Man, as a gift and not as an owner, does not take the world or others as possession. Man, as a gift, kills the animality within him and exalts, as Aristotle says, his rationality and intelligence (Di Sante, 1999). By choosing this path as the source of all law and meaning, man lives without killing, because he has killed his animality, and follows a different path, not starting from himself, but from the other (Levinas, 1974). The source of this path is the grace of the creative voice that has never been heard, but from a

silence that has never been silenced (Beauchamp, n.d.). Man, as a gift, accepts this founding grace and gives thanks.

In stark contrast to the animal, which also lives by grace, but knows nothing of this grace. It is clear that the human being is no longer in the garden created by the Creator. That territory is now a lost paradise. The human being finds himself already in a man-machine dialogue, dependent on the economic system that creates him. This man, who freely received the world and his neighbor, is rapidly traveling toward a world without humanity and without work; a world where problems will be solved by technology: by artificial intelligence and human genome editing; and where man will enjoy universal abundance. Man desires and yearns to be the master of the world, not a gift in the world. With this utilitarian totalitarian vision, man seeks to control and dominate humanity and his own future. If that is the case, who needs to dream of another future?

3.2. The Anthropocentric Narrative

In the Greek world, man lives in harmony with nature, cooperating with the rational order of nature, as a "universal symphony" that expresses the diversity of elements in an articulation of unity and obedience to the same principle.

In the Middle Ages, with no significant changes, a new element and a new meaning are introduced: "God, the absolute creator." Man is created in the image and likeness of God, and nature is the work of divine creation. The new element is that there is a coincidence between the law of nature and the divine law; and the new meaning presents God as a moral criterion that calls man to freely follow his unique path toward the Creator—God. Therefore, man acquires a different status from other beings, as a spiritual being that grants him a superior quality in the world he inhabits, but for which he was not destined. In Christianity, the icon of this relationship with nature and God was Francis of Assisi (1181–1226).

Regarding the Renaissance period, we can affirm that the two perspectives on man's relationship with nature are found: man is a microcosm in a macrocosm, living in a "universal sympathy" of harmonic proportionality between all beings. Man appears as a superior being in relation to the world but also distances himself from it to better understand it objectively.

In the Modern Age, particularly with Descartes, man is increasingly affirmed as the starting point of all true knowledge; nature is no longer understood through final causes and is instead explained by efficient causes. This period also marks the development of experimental sciences and the production of instruments and techniques for more diversified and effective intervention in nature. Science evolves and, in turn, allows for scientific progress that leads to an exponential increase (in contemporaneity) in man's power to shape nature according to his needs and interests. The anthropocentric perspective elevates to anthropocentrism by considering man as the center of the universe in relation to nature, reducing nature to a mere utility. Nature becomes an object in the hands of man.

It is in this deification of technology and science that Hans Jonas will denounce the "unregulated evolution" of technology. In this context, he proposes a new ethics and a new principle that can respond to technological civilization—the principle of responsibility—which is capable of predicting the effects of actions caused by emerging technologies. An ethics of prediction that acknowledges that the effect of each action always carries ethical significance for the future, formulating an ethics of responsibility as follows: A new imperative: act in such a way that the effects of your action are compatible with the permanence of authentically human life on earth; or act in such a way that the effects of your action do not destroy the future possibility of such life.

From Jonas' (2006) perspective, the promise of modern technology has become a threat. Technology, which was previously devoid of morality, now, because of its intervention in the subjective ends of human action, acquires ethical significance. Its constant demand for human inventiveness, both in what has yet to be done and in the maintenance of its artifacts, responds to human ambition in that it achieves success and crowns man with triumph.

4. From Technological Innovation to Artificial Intelligence

History teaches us that technology is inherent to human activity. We are always inventing and improving tools to serve humanity. Now, the technologies—Artificial Intelligence (AI)—that we create are shaping and inventing us (Kuskis, 2013). None of the technology, such as AI, invented so far, can change man entirely.

4.1. But What Makes Us Human?

What makes us human is not the mathematical, nor even the chemical or biological, but what surrounds us as individuals. That is, what goes unnoticed, the unspeakable, consciousness, the capacity for reflective intelligence in evaluating the good and the evil of actions through the consideration of moral values. The subject, the person, is not a thing; it is neither reifiable, instrumentalizable, nor objectifiable. The person, as an end in itself, is neither comparable nor equivalent. Its nature, being human, intrinsically acquires autonomy, freedom, and dignity.

It is due to the capacity for reflective intelligence that a person knows they have the freedom and autonomy to question the goodness, or lack thereof, of technology. Modern humans, if they want to dominate the confrontation between AI and Humanity, will have to apply basic ethical standards: be demanding in evaluating AI while understanding that their mission is not to stop progress but to humanize it.

Understanding the exponentiality of technology and its implications for the future of humanity is crucial. We must learn to imagine and then live with the changes. In the immediate future, which is ours, waiting to see is as bad as doing without thinking. We must look to the horizon, for the future is a constant definition and not something that simply happens. This means we must examine technology and question its necessity and appropriate use. The current time is no longer about the capacity to use a technology, but above all, how to apply ethics to technique; or, in other words, that technology meets the ethical demands of humanity.

The present time forces us to see, to be awake and attentive, to emerge in future scenarios, to discover how it would be to live in that future, because technology can be either paradise or hell, so we must be cautious and ask what is at stake: the how, when, how much, and for whom. The future is not a yes or no answer, but rather, it depends. If the questions of why and for what are heard, technology will be more balanced, but for this to happen, it is necessary to ask.

The answer lies in becoming better stewards of humanity. Each of us—a worker, a business leader, or any politician in their public representative role—must accept this task and act with responsibility, honesty, and truth. We must generate trust in the present and future of humanity because without an ethics of trust, technology, and AI without ethics will condemn the society dreamed of by Aristotle, whose goal is to achieve the just mean; the just mean, or measurement, is only possible when we research and invest in technologies that offer more effective ways to reduce or limit undesirable consequences.

Thus, organizations and institutions have the ethical duty to evaluate and judge whether this technology will diminish humanity. Evaluate and judge whether this technology will promote human happiness. Evaluate and judge the involuntary and potentially disastrous side effects and verify whether this technology will assume too much power. Finally, it is an ethical imperative of precaution to understand whether this technology will serve man or will serve itself. In other words, if technology (AI) should serve humanity and not man serve technology.

A technological future without humanity is a future without the human being. Humanity without an anthropology could become a technological orchestra supervised by superintelligent computers—machines and algorithms, cyborgs, and robots—or by those who dominate them!? The technological future, from this perspective, may even tolerate humans as pets or, at best, as a necessary evil; at worst, enslaved by the goddess of technology. It would be a desensitized, disembodied, and dehumanized society.

The curve of technological advancements continues to grow exponentially. This represents a cognitive challenge for us. Technological advances are increasingly combined and integrated. Radical advances, such as machine intelligence and deep learning, the Internet of Things, and human genome editing, are beginning to intersect

and complement each other. Technology seems to have no understanding of ethics, norms, or beliefs. These are matrices or values of human society. However, AI may, in the future, learn to read or understand our social or moral considerations, and even our moral dilemmas. But the question is: will it experience empathy, compassion, and exist as a "self" (Leonhard, 2017)? We live largely according to our values and beliefs, not according to data and algorithms. AI will never cease to be a computerized machine, and even with its immense capacity to analyze and simulate how humans act, it will be far from existing as a "self."

That is, despite simulating the most diverse and imaginative human interactions increasingly close to perfection, technology does not know, nor does it want to know, about happiness, personal satisfaction, personal fulfillment, emotion, or values and beliefs. It only understands logic, rational action, incompleteness, efficiency, effectiveness, and a simple yes or no response. The intelligent machine, to understand what happiness is, would first have to be happy. And to be happy, it needs to be incarnate and not nihilistic. Simulation is not duplication; mediated reality is not the experience of embodied reality (Leonhard, 2017).

For example, as Daniel Serrão says, if one day ectogenesis becomes possible, i.e., the generation of children outside of any woman's womb, without pregnancy or childbirth, it will be socially accepted, welcomed, and practiced as a great triumph of biological science, although for the author, this triumph reduces humanity itself. The human being, instead of being conceived, will be produced. Daniel Serrão also talks about quantum teleportation of a human body, the manufacture of cyborgs equipped with brain implants that will allow them to communicate telepathically with each other and with poor humans, who will become a subspecies with primitive and very limited forms of communication.

But is all this technology neutral and devoid of ethics until the moment we apply it? Is it only when applied by humans that it has ethical consequences? Or can we think that a technology with the potential to cause harm is not neutral, but already responsible for the act it causes?

5. Challenges of Artificial Intelligence: Opportunities or Threats

In medicine, for example, advanced technologies such as human genome editing, like CRISPR-Cas9, may soon help combat cancer and increase longevity. Another example of science's continuous surprises is what's already happening with reproductive techniques. After artificial insemination and surrogacy, the latest advancement allows a couple to have a child with DNA from a third person to prevent a genetic disease.

This technique is now legally practiced in the United Kingdom. For some, these scientific advances are remarkable; for others, they raise considerable ethical issues. At stake is a procedure, technically known as Mitochondrial Donation Treatment, used to prevent the child from inheriting mitochondrial diseases from the mother—rare, debilitating, and serious conditions present in maternal mitochondrial DNA. This triple genetic parentage raises an "ethical issue": the manipulation of human life during the generational phase and the destruction of embryos, which violates ethical principles such as "human dignity" and "genetic identity protection" (Neves, 2023).

Other examples can be discussed: robotics will increasingly invade operating rooms, and surgeons may no longer need to be physically present for procedures such as gallbladder removal or coronary bypass surgery—situations that are already real today. Recent scientific developments have revolutionized surgical procedures with the inclusion of robotics. The global market for surgical robots, which perform procedures both in-person and remotely (tele-surgery), has also been growing rapidly in recent years. Six million robot-assisted surgeries have already been performed worldwide, and these procedures can take place in locations that lack specialists, thanks to tele-surgery. Robotic technology is now used in minimally invasive surgeries, especially in urology, gynecology, general surgery, thoracic and abdominal surgery, and neurosurgery—especially due to the need for millimetric precision in surgical interventions.

AI, with its deep learning algorithms, can already read tomography scans faster than humans; natural language processing (NLP) can search for unstructured data in electronic health records (EHRs), and AI applications have become omnipresent in healthcare, with seemingly endless technical applications.

AI has the potential to reveal new data inputs and simplify interaction with health data, but the threat is the violation of privacy and the reservation of people's private lives, which is ethically reprehensible. Additionally, within the doctor-patient relationship, AI raises concerns about medical errors.

AI and its employment in healthcare will raise new challenges to the state of the labor market in healthcare as the sector adapts to new technologies. The first changes will affect the doctor-patient-professional relationship. Another aspect is that AI will replace workers in healthcare.

The replacement of workers in healthcare is already a concern. A 2018 Gallup Institute survey found that 71% of Americans believe AI will eliminate more jobs in healthcare than it will create. Just under a quarter of respondents believed healthcare would be one of the first sectors to lay off healthcare professionals due to the exponential rise of AI applications (learning tools). The most vulnerable are radiologists and pathologists, as many of the most impressive advances in AI are occurring in image analysis and diagnostics. “In recent years, AI-based imaging technologies have shifted from academic activity to commercial projects. There are tools to identify a variety of ocular and skin disorders, detect carcinomas, and support the necessary measurements for clinical diagnosis” (Stanford University, 2024). According to the report, some of these systems rival the diagnostic abilities of specialized pathologists and radiologists and can help alleviate specific tasks, such as counting the number of dividing cells in cancerous tissue.

Another issue is that AI presents a new set of challenges related to data privacy and security—challenges exacerbated by the fact that most algorithms require access to large data sets for training and validation. The exchange of vast amounts of data between different systems is an unknown territory for most healthcare institutions. The financial and reputational risks of a high-profile data breach, due to an inability to protect the data, is a relevant ethical, legal, and technical issue. Most institutions are advised to keep their data assets well-protected in highly secure systems that comply with HIPAA (Health Insurance Portability and Accountability Act), a set of standards healthcare institutions must follow to protect information.

Ensuring the privacy of all data will require updating data privacy laws and regulations to include data used in AI and machine learning systems, stated the Cloud Security Alliance (CSA). Privacy laws need to be consistent and flexible to account for innovations in AI and machine learning. Current regulations have not kept up with technological changes. HIPAA requires data de-identification; however, technology today can link de-identified data, resulting in identification.

This places AI in a regulatory gray area, making it difficult to ensure that each entity is required to protect patient privacy and will face consequences if they fail to do so.

Cyberattacks and concerns about patient privacy. Researchers at the University of Pittsburgh (TI Inside Online, 2024) found that cyberattacks using falsified medical images can deceive AI models. The study sheds light on the concept of “adversarial attacks,” in which perpetrators aim to alter images or other data points to cause AI models to draw incorrect conclusions. Researchers trained a deep learning algorithm to identify cancerous and benign cases with over 80% accuracy. They then developed a “Generative Adversarial Network” (GAN), a computer program that generates fake images by shifting cancerous regions into negative or positive images to confuse the model. The AI model was deceived by 69.1% of the falsified images. Of the 44 positive images made to appear negative, the model identified 42 as negative. Of the 319 negative images altered to appear positive, the AI model classified 209 as positive. As stated by Shandong Wu, Ph.D., The purpose of this study is to show that this type of attack is possible and can lead AI models to make incorrect diagnoses—which is a major patient safety concern. Understanding how AI models behave under attacks in medical contexts, we can begin to think about ways to make these models more secure and robust.

On the other hand, AI can also help alleviate the stress and burnout of doctors and nurses, reducing clinical absenteeism. The COVID-19 pandemic affected doctors, nurses, and other caregivers, who may reduce their working hours in advance. Automating some routine tasks that occupy a doctor's time, such as documentation (electronic health records), administrative reports, or even triage of CT scans, can be beneficial for doctors to focus on the complicated challenges of patients with rare or severe conditions.

In healthcare, it is believed (and AI experts also believe) that the balance point for AI in healthcare will be the combination of human experience and digital enhancement. Each type of intelligence should be adjusted to the needs, and together, human experience and AI will improve care delivery. For example, AI is ideally equipped to handle challenges that humans naturally cannot face, such as synthesizing gigabytes of raw data from various sources in real-time for a hospitalized patient. But no one expects a robot to converse with the family of the patient about treatment options or to provide compassionate and supportive care if the disease leads to death.

While it is true that AI brings benefits and the total, online machine body knowledge, expanded for technological performances we cannot yet imagine, will make medical activity almost exclusively preventive, total knowledge of the pathways leading to illness will create a rigorous science of disease prevention. The consequences, according to Daniel Serrão, “are both good and bad; some will be very bad and dangerous.”

5.1. From Telemedicine to Telesurgery

Telemedicine consists of the provision of healthcare services through information and communication technologies, where the healthcare professional and the patient are not physically present in the same location. This involves “the transmission of health data and information through text, sound, images, or other necessary means for the prevention, diagnosis, treatment, and monitoring of patients,” and is present in various medical specialties, “from teleradiology to telesurgery, including teleconsultations” (Pereira, 2020).

In fact, telemedicine is not a recent reality, but it has gained significant momentum in recent years—largely due to the digitization of health data, AI, and microcomputers linked to health information—enabling the adoption of new resources such as the provision of remote healthcare services with greater efficiency. A recent example of this potential was experienced during the COVID-19 pandemic, where various health systems published exceptional guidelines for remote medical care during the public health emergency.

In our view, and in the view of many experts, the pandemic caused by COVID-19 represents an important milestone in the history of telemedicine and access to healthcare (Eduardo & Rafaella, 2020). The benefits that can be highlighted are: “increased efficiency in medical care, consultations for populations located in remote areas from health centers and hospitals, effective support for the lack of specialized professionals, or where medical practice conditions are limited,” as is the case in Portugal, which faces a shortage of doctors, particularly in rural areas (a problem affecting developing countries worldwide). Therefore, the use of AI tools may not be a bad idea for doctors struggling to meet the needs of numerous complex cases and patients requiring significant care investments.

Regarding telesurgery, the use of robots makes surgery safer and more precise by eliminating the natural tremor of human hands; a micro camera amplifies the surgeon's view and decision-making during surgery. Specialists argue that this makes the surgery faster and more accurate. The robot precisely replicates the movements of the doctor's hands, and it is certain that AI technology is already working toward enabling the robot to one day perform an intervention without the human factor involved (Eduardo & Rafaella, 2020). These technologies could change the entire logic of healthcare, social security, and employment.

The technology of Artificial Intelligence, computing, and deep learning will produce recursive improvement—self-amplification (autonomous robots that reprogram themselves). According to some experts, this “explosion of intelligence” could lead to the emergence of superintelligence. AI will learn and think faster than humans (Leonhard, 2017), with the escalation of monitoring our digital lives: surveillance, reduced privacy, loss of anonymity, digital identity theft, security, and more. All these technologies use sensitive health data from the

patient, raising questions about the reflection on the values and ethical principles that should govern this data handling, especially regarding the patient's consent.

6. Ethical Values and Principles Applied to Artificial Intelligence

The values and ethical principles applied to AI remain the same as those principles and values applied to human life and intelligence. Norms and regulations should align with domestic law and international law, including the United Nations Charter, as well as being in harmony with international objectives regarding social, political, environmental, educational, healthcare, scientific, and economic sustainability.

6.1. What Ethical Values Should We Promote and Safeguard?

First and foremost, the inviolable, inherent, and intrinsic value of Human Dignity. Every human being forms the foundation for the system of human rights and fundamental freedoms. Each person enjoys this value, which is universal, ineffable, inalienable, intrinsic, and interdependent.

Therefore, the value of dignity demands the safeguarding of the principles of respect and protection of human rights, which are the guarantee of human dignity enshrined in the Human Rights Charter and democratic constitutions. It is from this indelible value that justice and equity are ensured, regardless of a person's condition: race, color, ancestry, gender, age, language, religion, ideology or political opinion, nationality, ethnic origin, or social and economic background.

Under no circumstances can an individual or community be harmed or subordinated, whether physically, economically, mentally, politically, or culturally, in relation to the development of Artificial Intelligence. AI systems must enhance, not diminish, the quality of life for every human being, and this definition of quality of life should be open to individuals or groups, as long as no human rights violations or abuses occur.

The value of human dignity calls for the principle of vulnerability. Interaction with AI systems should promote assistance and care for the most vulnerable, as well as for those in vulnerable situations—children, the elderly, and individuals with disabilities or illnesses. In such situations, AI must never objectify or commodify the human person, as doing so would ethically violate their dignity and infringe on fundamental rights. Human rights, as a human value, must be protected and respected by AI systems. Governments, institutions, and universities must respect human rights as a limiting framework for AI when they cause harm.

The environment and ecosystem are values of humanity and existential necessities. Environmental prosperity invokes the ethical principle of social responsibility toward future generations. AI must not serve interests that hinder humanity from enjoying the benefits of nature. AI can and should foster peace and environmental cohesion. All those involved in AI development should adhere to the ethical principle of precaution and comply with applicable standards to ensure that the planet's sustainability becomes a reality and to prevent the unsustainable exploitation, use, and transformation of natural resources.

Diversity and inclusion are valued principles that must be guaranteed in society. AI should provide tools that ensure the respect, protection, and promotion of these values—of inclusion and diversity. Lifestyle choices and beliefs cannot be excluded from these systems. The value of inclusion refers to the ethical principle of cooperation to transform disadvantages into advantages; to reduce the gap separating technological infrastructural weaknesses, education, and skill and competence. From the ethical principle of cooperation, the principle of solidarity is derived to bridge differences and promote diversity.

AI should also support all technological systems based on the value of Justice, in order to ensure peaceful societies and fair distribution of benefits. AI systems must contribute to the interconnection of society as a whole. Interconnection is based on the understanding that each person is part of a whole and that the whole thrives when all parts also thrive.

Our values and ethical principles are what guide and compel us. Therefore, in the face of the digital world, if we do not want to create a digital atomic bomb (as was the case with the analog atomic bomb), a reality we would

regret the consequences of, we must commit to the human team that can define which intelligent machines are most likely to promote the flourishing of humanity, rather than just the growth and development of technology (Leonhard, 2017). To ensure this, the European Union's recommendations are important and relevant, pointing to some fundamental requirements: 1) human oversight in decision-making; 2) technical and security standards—AI systems must be safe, robust, resilient, and trustworthy, in order to ensure that any accidental or intentional harm can be minimized and prevented; 3) data privacy—ensuring that data fully respects privacy, protection, and personal integrity.

6.2. What Ethical Principles Should Guide AI?

In 2021, the World Health Organization (WHO) released its first global report on the ethics and governance of AI in healthcare. The WHO emphasized the potential health disparities that may arise as a result of AI, primarily because many AI systems are trained with data collected from patients in high-level care settings.

The WHO suggested that ethical considerations should be taken into account during the design, development, and deployment of AI technology. Specifically, it recommended that individuals working with AI operate according to the following ethical principles: protect human autonomy; promote human well-being, safety, and the public interest; ensure transparency, explainability, and intelligibility; promote accountability; ensure inclusion and equity; promote responsive and sustainable AI.

- Protection of Autonomy: This means that humans should retain full control over AI systems. These systems must not, and should not, diminish human control over healthcare systems.
- Safety, Well-being, and Protection: AI must be able to eliminate unintended harm and vulnerabilities during the system's lifecycle, ensuring the protection and safety of human beings. It should also take into account mechanisms that safeguard privacy and the confidentiality of personal life.
- Ensuring Transparency, Explainability, and Intelligibility: Information and documentation should be truthful. Technologies must be explained in accordance with their audience; the rigor of information and the accuracy of explanations are critical ethical factors in understanding the use of AI in healthcare.
- Proportionality and Do No Harm: AI technologies do not, on their own, guarantee the social cohesion of humanity. All AI systems should be appropriate for the context and needs. They must also ensure risk assessment procedures and adopt measures to prevent harm. The ethical principle of proportionality helps to build: a) methods proportionate to their purpose; b) not infringing fundamental values or violating human rights; c) being appropriate for the context and based on robust and rigorous scientific foundations. This implies that if technical possibilities could impact life decisions or result in death, the final human determination must be applied. AI systems should not and cannot be used for social grading, mass surveillance, or individual surveillance.
- Equity and Non-Discrimination: AI should promote social justice and safeguard equity and non-discrimination. It implies ensuring that the benefits AI can offer are available to all. Inclusive access to AI systems with relevant services and content, respecting diversity, should be ensured to avoid digital exclusion.
- Guaranteeing Inclusion and Equity: AI in healthcare and for individuals should include everyone in healthcare needs to ensure equity, regardless of any social, cultural, economic conditions, or other vulnerabilities.
- Promotion of Responsive and Sustainable AI: AI technologies should only be applied if they serve humanity and meet the needs of each human being. Their sustainability requires an ethical perspective that favors the environment and a healthy, non-fundamentalist ecology.

7. Regulatory Instruments

What can and should we do to ethically regulate and minimize the risks or threats associated with AI?

The Portuguese government, in its “Portuguese Charter of Human Rights in the Digital Era,” states in Article 9 that “the use of artificial intelligence should be guided by fundamental rights, ensuring a fair balance between

the principles of explainability, safety, transparency, and accountability; it should take into account the circumstances of each specific case and establish moral criteria to avoid forms of discrimination" (Article 9, Law No. 27/2021, May 17, amended by Law No. 15/2022) (World Health Organization, 2021).

It also emphasizes that regarding the creation of robots, the principles of beneficence, non-maleficence, respect for human autonomy, and justice are applicable, as well as the principles and values enshrined in Article 2 of the Treaty of the European Union, including non-discrimination, tolerance, and the inviolability of human dignity, which must be respected and protected. Human dignity constitutes not only a fundamental right in itself but also the very foundation of fundamental rights (Article 3).

At the European level, on April 8, 2019, the European Union published the "Ethical Guidelines for Trustworthy AI," based on the premise that AI should be lawful, ethical, and robust, establishing seven requirements that AI must necessarily meet. These are: 1) AI supervision must be human-led; 2) Technical robustness and safety—systems must be resilient and secure; 3) Data privacy and protection; 4) Transparency and explainability of AI systems; 5) Diversity, non-discrimination, and equity—biases lead to negative implications, such as marginalization of vulnerable groups; 6) Social and environmental well-being and concern for present and future generations; 7) Accountability and responsibility for AI systems.

8. Informed Consent and AI—Applicability

It is imperative that informed consent be protected in the domain of AI tools and their various applications. The collection and storage of sensitive data raises concerns among individuals. The recent fundamental right to digital "forgetfulness" of personal data, except under specific circumstances (Correia et al., 2021), necessitates a reconsideration of the informed consent doctrine to better suit the digital age. Respect for privacy rights and the duty of transparency may create some difficulties. While transparency is essential for building trust, it can also pose a risk to individual privacy and the protection of personal data. That is, while the explainability of closed AI systems is important, excessive transparency can undermine the privacy process (CNECV, 2024).

As the National Ethics Council for Life Sciences (CNECV) states, the processes of anonymization and pseudonymization have shown flaws, suggesting that this risk be minimized by resorting to synthetic data (CNECV, 2024).

8.1. Consent in Robotic Surgery and Telemedicine Surgery

It is estimated that the Da Vinci robotic surgeon (manufactured by Intuitive Surgical) has already performed minimally invasive surgeries on about six million people worldwide. In areas without specialists, these interventions can be performed through telemedicine surgery.

As noted, there are numerous benefits of robotics in surgery—elimination of natural hand tremors, greater flexibility of robotic arms that can rotate 360º, increased precision in cutting and suturing tissues, leading to reduced blood loss and smaller scars. However, the complexity of the human body and the inevitable influence of external factors lead to uncertainty, an inseparable attribute of medical practice, and robotics in surgery does not eliminate unpredictability in medical treatment. Some examples of such unpredictability are already the subject of legal cases.

In the U.S. context, legal disputes over robotic surgery with Da Vinci robots have centered on violations of the duty to inform and product liability. While most cases have been settled out of court, the *Taylor v. Intuitive Surgical, Inc.* case (2017) offers a landmark example of judicial scrutiny regarding informed consent in robotic-assisted surgery. In this decision, the Supreme Court of Washington evaluated not only the clinical risks associated with robotic procedures but also systemic communication failures and the extent of the manufacturer's duty to inform hospitals, not just individual physicians. The ruling challenged conventional frameworks of medical liability and reinforced the necessity to reconceptualize informed consent in contexts of algorithmic mediation and robotic delegation.

In robotic surgery, as with any medical intervention, the duty to inform and clarify is an ethical duty, a good clinical practice, and an essential component of the doctor-patient trust relationship. This duty is embodied in the ethical and legal principle of informed consent. Its neglect signifies a breach of the relationship between the healthcare professional and the patient in terms of autonomy and self-determination.

In the case of an intervention using AI tools such as telemedicine surgery (robotic surgery), the doctor must clarify, in addition to clinical explanations, the methodology that will be used to perform the surgery. The patient has the right to know the risks and advantages of robotic surgery. In the event of damage, whether physical or moral—physical damage refers to harm to physical integrity, and moral damage refers to harm to personal integrity—if the lack of informed consent is proven, compensation is due for the deprivation suffered, as stated in the Portuguese Constitution, which affirms that no one can be harmed in their physical or moral integrity. This is also referenced in the Civil and Penal Codes, in the respective legal articles on informed consent. It is the victim's responsibility to demonstrate that the damage was caused by a risk they should have been informed about to make an informed decision on whether to accept the treatment, in order to establish and verify the causal link between the omission of information and the damage.

Currently, examples of conflicts between patients and doctors using robotic surgery are numerous. In 2009, a surgery involving the "Da Vinci" robot, the Pennsylvania District Court in the United States resolved the case *Mracek v. Bryn Mawr Hospital and Intuitive Surgical* without analyzing the merits (summary judgment) on the grounds that the patient did not provide sufficient direct or circumstantial evidence of a causal link between the device defect and the damage suffered. The case dates back to 2005, when, during a minimally invasive surgery, the robot began displaying error messages, and the team attempted to restart the robotic platform several times in an effort to continue the surgery. A technician from Intuitive Surgical had to intervene to try to fix the issues, including attempts to reposition the robot's arms, but was unsuccessful. Due to the inability to restart the robotic intervention, the medical team abandoned the robotic platform, and the surgeon completed the surgery using traditional laparoscopic equipment. The time between the suspension of robotic surgery and the initiation of conventional surgery was approximately 45 minutes.

This is an example of many situations where distance robotic surgery can be interrupted and replaced by conventional surgery, performed by a different doctor rather than the original surgeon. This issue is crucial because the initial premises are altered without the patient's consent. As a result, the change in procedures sometimes leads to larger scars on the patient's body, which were not anticipated in the consent and clarification process of undesirable effects. Moreover, the conversion of the procedure may result in "longer surgical time, more time under anesthesia, and/or the need for additional or larger incisions and/or increased complications." All of this information should be provided to the patient beforehand to allow them to make a more informed decision.

This case, along with others, demonstrates the possibility of complications during robot-assisted surgeries, leading to the need for conversion to an open surgery. Thus, the risks associated with robotic surgery become evident.

In this sense, Deborah Dubeck, in the article "Robotic-Assisted Surgery: Focus on Training and Credentialing," outlines specific aspects of informed consent in robotic surgery: 1) the patient needs to be informed and clarified on more than just the general risks; 2) the benefits and alternatives associated with the procedure; 3) the risk of robotic failure and the implementation of a contingency plan; 4) the possibility of converting to an open procedure. All of these issues must be addressed in the informed consent process with the patient, which increases the need for the healthcare professional operating robotic AI systems to clearly explain and clarify the benefits and risks, pros and cons of robotic surgery, alongside other therapeutic alternatives.

In a hypothetical case where a doctor remotely performs coronary artery bypass surgery and, during the procedure, the robotic arm makes an unexpected movement, cutting a coronary artery and causing significant damage to the patient, the professional may face legal action for damages. However, it is crucial to understand

the causal link between the medical conduct and the damage suffered. One might conclude that the doctor acted prudently, diligently, and with the required knowledge, and that the damage was caused by the time delay between the surgeon's hand movements and the robot's response.

8.2. Information Required for Free and Informed Consent in Robotic Surgeries

The following information is suggested for inclusion in the informed, free, and clarified consent process for robotic surgeries:

1. The possibility of interruption of telemedicine surgery due to internet connection issues or equipment failure.
2. The existence of a time delay between the surgeon's movements and the robot's response, which may lead to an adverse event.
3. The technical risks arising from software failure or technological limitations.
4. The potential for illicit third-party access to the patient's health data stored on a network.
5. Clear explanation to the patient of the differences between robotic surgery and conventional surgery for the specific case.
6. Demonstration of the surgeon's professional and technical skills to perform robotic interventions, clarifying their adequacy and technical expertise with robots.

Numerous cases of errors and accidents in telemedicine surgeries have occurred. One such case involved a patient in 2015 who died after undergoing robotic surgery at Freeman Hospital in Newcastle, England. The robot made a sudden movement, tearing part of the heart during the surgery. The doctor admitted to insufficient capacity and technical training to operate with the technology. This ethical and legal responsibility does not solely fall on the unprepared professional but also on the hospital for failing to adopt appropriate policies for robotic surgery training.

Thus, the doctor also has the duty to inform and clarify to the patient undergoing such interventions about their technical capacity:

1. The level of technical training and experience in robot-assisted surgeries.
2. The hospital's robotic surgery training and education policy.
3. Whether the specific robotic surgery has been performed by anyone else at the same hospital or another hospital within the country.
4. The benefits and risks of robot-assisted surgery in comparison to conventional surgery.

Patients who undergo telemedicine surgery, as per medical recommendation, must be informed about the surgeon's experience with the recommended robotic procedure. The doctor should discuss their surgical experience and explain all associated risks (Massachusetts Board of Registration in Medicine Guidelines).

In this sense, informed consent for robotic surgery, whether performed in person or via telemedicine (tele-surgery), should include at least 12 essential items (Eduardo & Rafaella, 2020), as follows:

1. A description of how robot-assisted surgery is performed and its main advantages.
2. Differences between robotic surgery and conventional surgery for the specific case.
3. General information on the expected benefits and potential risks associated with using the technology.
4. Clarification of the surgeon's aptitude, skill, and experience with robot-assisted surgeries.
5. Information about the robotic surgery training and education policy of the hospital where the procedure will take place.
6. Whether the robotic surgery has been performed by others at the same hospital or any other healthcare institution in the country.
7. A note on the possibility of interruption in telesurgery due to internet connection issues or equipment failure.

8. Information about the possibility of complications during surgery due to system or robotic equipment failure, leading to a conversion from robotic surgery to conventional (open) surgery, potentially with a different doctor performing the surgery than originally planned with the patient.
9. Information that the conversion from robotic to conventional surgery (open) involves larger incisions and more time under anesthesia, increasing risks for the patient.
10. Explanation that in telemedicine surgery, there is a time delay between the surgeon's hand movements and the robot's response, which could cause an adverse event.
11. Exposure to other technical risks from software failure or technological limitations.
12. Transparent explanation of how the patient's data is stored on a network and the possibility of illicit third-party access.

9. Patient, Digital Assistants (AI), and Informed Consent: From the Right to Information to the Right to Explanation

Informed consent from patients regarding artificial intelligence (AI), particularly health assistance robots and diagnostic analysis through intelligent software, cannot exclude the patient's right to information, explanation, and justification regarding the utility and use of these technologies. As previously mentioned, telemedicine, teleconsultations, and telesurgeries have benefits and risks. Logically, the technology we now discuss also carries its own advantages and disadvantages.

The various possibilities that AI offers in healthcare, such as the smart surgical robot developed by the U.S. Department of Defense in 2018 or the STAR (Smart Tissue Autonomous Robot) capable of analyzing case circumstances and choosing the most appropriate technique for the specific situation, are already realities.

A brief note about AI applied to medical practice serves to highlight some of the many benefits. However, as we know, these potential benefits are accompanied by risks, raising important ethical and legal questions, particularly concerning informed consent.

Given the possibility of AI causing unpredictable harm due to machine learning advancements, along with the necessity to ensure algorithm reliability, the same importance should be given to research guided by bioethical principles: beneficence, non-maleficence, autonomy, justice, and informed consent. However, given the sensitive nature of the ethical issues surrounding AI, these bioethical principles should be complemented by additional ethical and legal principles to ensure fairness and equity in addressing the complexity of AI and robotics, aiming to avoid harm to physical and moral integrity, which is a pillar of informed consent.

Respect for human autonomy is the primary ethical imperative that professionals in the field of AI must always uphold, ensuring that technology is developed, implemented, and used reliably. Intelligent systems should be designed to enhance, complement, and empower human cognitive, social, and cultural abilities, with human supervision and control always guaranteed.

Respecting the autonomy and self-determination of a patient undergoing AI-supported diagnostic analysis, such as through Watson for Oncology, means informing the patient that the technology has a degree of fallibility, and that, ultimately, the decision lies with the doctor. As remarkable as Watson for Oncology is in data processing, we cannot ignore that it makes errors. AI should serve as a support for medical decision-making, without intending to replace it.

The principle of explainability is equally crucial to maintaining trustworthy AI, following the guidance from the European Parliament mentioned earlier. The decision-making processes of intelligent systems need to be transparent, allowing, whenever possible, an explanation of a particular result or decision, along with identification of the entity responsible for it. Human autonomy and explainability demand a new ethical standard for informed consent when a person is receiving healthcare supported by AI. This includes:

- Clarification of information is critical, but it must also include the right to explanation and justification for the procedures performed by AI, promoting transparency throughout the artificial intervention, including traceability of the process.
- The explainability of decisions made by the intelligent system.
- Communication in a way that allows the patient to accept or refuse interaction with AI.

10. Final Note

The narrative from the beginning (Couto, 2013), in the Book of Genesis, teaches that by not embracing the nature of the world and merely possessing and using it as an object, man disrespects the free hospitality that humanity/universe offers him. Nature cannot be used at will, as an object to discard (Thayse, 1998). A man who treats humanity as an object is not a man humanized by the tenderness of fragile nature (cf. Heschel, 2001; Couto, 2013). A nature enslaved and objectified by man is a nature in which everything is reduced to mere numbers. Indeed, when man reduces and instrumentalizes nature as objects and numbers, it is man himself who is reduced to an instrument, i.e., to an object.

History teaches us that technology is inherent to human activity. We are constantly inventing and improving tools to serve humanity. Now, the technologies we create are shaping us and inventing us (Kuskis, 2013). None of the technology invented so far can change man entirely. What makes us human is not the mathematical, chemical, or biological. But what surrounds us. That is, what goes unnoticed, the unspeakable, consciousness, the ephemeral, and the un-objectifiable. Robotics and AI are not inevitabilities or fatalities but have a purpose. Technologization is not and cannot be a fatality but a tool whose purpose is to serve humanity.

Thus, while we have an ethical responsibility to not impede progress, we also have the ethical duty to ask about its purpose: for what, for whom, when, and how. We must be companions, not spectators, of this digital era and transformation, engaging in a "You to You" dialogue—man and technology—where the first "You" can care for the second and extract the best for the humanization of the individual. This "You to You" dialogue is one of open hands, between the humanities and the sciences, for building a more just and equitable humanity.

If we fail in this, we fail as humans.

It is important to underscore that this contribution is normative and conceptual in nature. Rather than producing empirical generalizations, it provides ethical reasoning and interpretative clarity to guide professional practices and policy frameworks in AI-driven healthcare. Future research should explore empirical data from healthcare practitioners, patients, and AI developers, as well as undertake comparative legal studies across different jurisdictions. Additionally, further inquiry into the operationalization of ethical-by-design principles—embedding ethics directly into AI system architecture—could provide pathways to make informed consent in digital healthcare more transparent, traceable, and enforceable.

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