ETHICAL DESIGN IN MEDICAL AI ROBOTICS: BETWEEN INNOVATION AND RESPONSIBILITY

Roxana-Mariana Nechita [1, 2, *], Marilena-Iuliana Nechita [3, 4]

[1] National Institute of Research and Development in Mechatronics and Measurement Technique, 6-8 Pantelimon Road, Bucharest, Romania
[2] National University of Science and Technology Politehnica Bucharest, Doctoral School of Entrepreneurship, Engineering, and Business Management
[3] National University of Science and Technology Politehnica Bucharest, Faculty of Industrial Engineering and Robotics, 313 Splaiul Independentei, Bucharest, Romania
[4] Metaplast SRL
* Corresponding author. E-mail: roxana.nechita2000@gmail.com

Abstract: The accelerated development of artificial intelligence-integrated medical robots poses major ethical challenges, particularly in sensitive areas such as surgery and remote healthcare. This paper investigates how ethical principles can be incorporated into the design of these systems from the outset, through an 'ethics by design' approach. It analyses the specific regulatory framework and highlights the need for proactive, enforceable regulation. A conceptual and theoretical analysis identifies recurring dilemmas related to algorithmic transparency, privacy, accountability, and meaningful human control. The paper proposes a conceptual model that incorporates ethics as an integral part of the technological process, rather than an afterthought. The paper's value lies in clarifying the need for a systematic ethical infrastructure and multidisciplinary collaboration in the design of autonomous robots. It also emphasises the urgent need for unified standards to ensure responsible, integrity-centred development.
Keywords: ethics by design; artificial intelligence; medical robotics.

1. Introduction

Over the past few decades, the development of artificial intelligence (AI) has brought about a profound transformation in the way technology is conceived, integrated, and utilised within society [1]. Autonomous robotic systems that can learn and adapt pose some of the most complex ethical challenges due to their potential to interact directly with human beings [2] and influence decisions that could significantly impact the privacy, dignity and security of individuals [3]. In this context, researchers involved in designing and implementing these systems have a key role to play in ensuring that technological development respects fundamental societal values.While the scientific literature reflects a growing concern for establishing ethical principles applicable to AI [4], the practical application of these guidelines in technological research is often ambiguous or insufficiently regulated. Tensions arise between innovation and accountability due to divergences between normative-idealistic and technological feasibility-oriented approaches, especially in the absence of clear operational standards. Furthermore, studies on the social impact of intelligent robots highlight significant ethical risks [5], such as privacy breaches, autonomous decision errors, behavioural manipulation, and a lack of accountability [3].

This paper aims to investigate how ethical and integrity considerations can be integrated into the research and development processes of AI robotic systems from the stage of defining the technological concept. To this end, the existing regulatory framework will be analysed and recurrent ethical dilemmas identified. A conceptual model of 'ethics by design' will then be proposed to support researchers in making responsible decisions. The study aims to strengthen the integrity-based professional character relevant to academic, industrial and institutional settings.

2. Theoretical Framework

Analysing the ethics of AI-based robotic systems in research and development requires a multidisciplinary approach located at the intersection of the philosophy of technology, ethical responsibility theory, and technological innovation studies [6], [7]. At the core of this theoretical framework lies the concept of 'ethics by design', involving the incorporation of ethical considerations throughout the technological design and development process [8], [9]. Unlike the reactive model, where moral issues are addressed only after the social consequences of the technology have emerged, this approach proposes a systematic anticipation of ethical risks.

A notable example of this principle in action is telesurgery, where AI-powered robotic systems assist surgeons in performing minimally invasive procedures, often from a remote location [10]. While this technology allows for greater autonomy in robotic arms and advanced intraoperative image analysis, medical and regulatory consensus still demands the active presence of a human physician to ensure the integrity of the medical procedure [11], [12] and protect patients [13]. Systems such as CorPath GRX and NeuroArm can perform autonomous catheter manipulations and high-precision microsurgery [12], but only in direct collaboration with a human operator who makes decisions, provides validation and intervenes in cases of non-compliance [10], [14]. Therefore, human–machine interaction is complementary, not substitutive [15]. AI-powered autonomous robots interact directly with users, manage personal data and navigate crowded spaces [16], [17]. Such systems must be designed not only for operational efficiency, but also to comply with data protection rules, avoid collisions, recognise atypical behaviour and provide services in an ethical and non-discriminatory manner [17]. However, the absence of human involvement in the design, testing, and supervision stages could result in scenarios involving privacy invasion or algorithmic discrimination [3], [4], which are incompatible with the standards of a democratic society. Therefore, the need to model robotic systems within an ethical framework is imperative in both high-risk environments, such as healthcare [13], and those involving extensive social interaction, such as education and public services. The meaningful human control theory [18], together with the concepts of collective responsibility and ethics by design, provides a solid foundation for developing technologies that work and respect fundamental human values. The research is also grounded in the principles outlined by international responsible AI initiatives, such as the OECD AI Guidelines [19] and the European Commission's ethical principles for AI [20], which promote values such as transparency, fairness, accountability, and privacy [21]. These principles are essential for developing a regulatory framework for research activities and for making design decisions in an ethically sound manner.

In essence, the proposed theoretical framework provides a coherent set of concepts and theories that enable us to grasp the intricacies of advanced technological research and establish a robust foundation for formulating ethical principles for autonomous robotic system development.

3. European Ethical Principles

The European Commission's Directorate-General for Research and Innovation published a reference document entitled “Ethics by Design and Ethics of Use Approaches for Artificial Intelligence” [22]. This document provides a conceptual and methodological framework for integrating the ethical dimension into all stages of an artificial intelligence system's lifecycle. While not legally binding, this guide serves as a valuable resource for researchers and developers engaged in EU- and non-EU-funded projects. The principles set out in the document are supported by the findings of relevant European initiatives, such as the SHERPA and SIENNA projects. The guide is based on the recognition that ethics applied to autonomous systems cannot be dealt with retrospectively, but must be integrated from the conception of the technology. The 'ethics by design' approach proposed in the guide implies translating general principles into concrete requirements for the design, development, and use of AI systems.

The ethical framework for responsible AI defines six core principles: respect for human agency, privacy and data governance, fairness, well-being, transparency, and accountability with human oversight. These principles are converted into detailed operational requirements integrated across a six-stage development structure for verifiable, auditable systems. Meaningful human control over algorithmic decisions is emphasized, especially when they affect fundamental rights like health or life. This is particularly critical for medical robots, where the system architecture must explicitly incorporate traceability and explainability mechanisms. This ensures patient safety and addresses legal liability by allowing medical personnel to understand and audit the AI's clinical decisions.

Another significant aspect introduced by this document is the distinction between the ethics of design and the ethics of use. The former aims to integrate normative principles into technological architecture, while the latter involves maintaining ethical compliance when using the system in real-life contexts. This can be achieved through measures such as continuously training users, implementing clear mechanisms for reporting incidents or ethical dilemmas, and constantly monitoring the system's social impact. This approach enables risks such as malfunctioning, function creep, and the abusive externalisation of responsibility to the algorithm to be anticipated.

In the context of developing surgical robots, adapting the principles and requirements of the “Ethics by Design” guideline means translating normative generalisations into operational tools and procedures specific to each design and use phase. Thus, at the goal-setting level, the obligation to include a “surgeon-in-the-loop”, who has the final decision-making authority over any autonomous action and can immediately stop the robotic operation in the event of any deviation from the protocol, will always be added. When defining technical requirements, specifications must include details of all intra-operator parameters (e.g. force, voltage, positioning and video streaming) so subsequent auditing can reliably reconstruct the decision-making process. Rigorous medical labelling protocols validated by multidisciplinary teams are required for data collection and preparation to eliminate any diagnostic or treatment bias. During

the detailed development phase, explainability modules will be integrated to explain the algorithmic reasoning in real time. Simulated tests with virtual patients will verify how the system reacts to unforeseen emergency scenarios. Finally, the ethics of use imply implementing a continuous training programme for surgical teams that includes simulated error cases, as well as an ethical incident reporting mechanism managed by an independent monitoring committee to ensure the continuous improvement of the safety and ethical compliance of surgical robots. While adopting this approach inevitably requires additional effort from the developers and institutions involved, the long-term benefits are clear: reduced reputational and legal risks, increased user confidence, facilitated ethical certification and, most importantly, a promoted model of responsible innovation. In a global context characterised by a lack of harmonised mandatory standards, the document developed by the European Commission could serve as a valuable reference for the development of public policies, good practice guidelines, and accreditation mechanisms in the field of medical AI.

In conclusion, integrating the European guidelines into medical robotics research and innovation provides a coherent framework for translating human values into technological architecture. The "ethics by design" approach, supported by the European Commission, thus becomes a prerequisite for developing a responsible, safe and transparent artificial intelligence ecosystem that will have a lasting positive impact on medical practice and wider society.

4. Discussion

With rapid advances in AI and robotics, intelligent surgical systems are transforming medical practices. This shift brings technical innovations and significant ethical, legal and regulatory challenges. In their paper, O'Sullivan et al. [23] explore the ethical, legal and regulatory challenges related to the use of AI and autonomous surgical robots in healthcare. They analyse how these emerging technologies could transform surgery and emphasise the need for clear regulations concerning liability, cybersecurity and patient safety. Drawing parallels with the levels of autonomy in the autonomous vehicle industry, the authors suggest that robotic surgery should always have a 'surgeon-in-the-loop' to oversee robotic interventions. They also discuss the military applications of autonomous robotic surgery, where these systems could save lives in conflict zones through remote interventions. They highlight the challenges of hacking and cyber vulnerabilities in this context. Finally, O'Sullivan et al. [23] advocate the development of bespoke legal frameworks and safety standards for autonomous surgical technologies, stressing the importance of certification and the ongoing monitoring of these systems to safeguard patients.

The study by Collins et al. [24] reveals that integrating AI into robotic surgical training can significantly improve performance and standardise the educational process. However, it also raises many key ethical challenges. Firstly, the study emphasises the importance of ensuring the confidentiality of data and compliance with ethical regulations when collecting and using pre-trained data, including obtaining informed consent from patients and surgeons. Second, it highlights the importance of transparent AI algorithms to enable clear and reproducible interpretation of automated decisions, thus avoiding poorly explainable "black box" models. Furthermore, expert consensus highlights the need to standardise data labelling methods and adopt objective, open metrics for performance evaluation to optimise the machine learning process. Multidisciplinary involvement (including clinicians, engineers, researchers, patients, and ethicists) is also considered vital for the development and regulation of AI systems. In terms of practical implementation, clear accountability protocols and remediation programmes for any competency gaps identified through AI are recommended. While the technology is still in its infancy, its potential benefits are significant. However, adoption must be based on scientific rigour, data protection and careful consideration of the ethical impact to ensure the safe, effective and equitable use of robotic surgical training.

Morris et al. [25] conducted a systematic examination of the ethical, legal and financial aspects of integrating AI into surgery. They highlight the challenges posed by the opacity of black-box algorithms, which can generate difficult-to-interpret decisions and perpetuate biases due to the limited quality and representativeness of the available data. The study emphasises the need for transparency in AI decision-making and the responsibility of physicians and developers in the context of legal liability, particularly in autonomously assisted surgery. In terms of regulation, the study emphasises the importance of implementing standardised protocols such as SPIRIT-IA and CONSORT-IA, which are aimed at ensuring the quality and safety of AI applications in surgical research and practice. Regarding finances, the authors discuss the high initial costs of AI and robotics technologies, as well as their potential to reduce operational costs and enhance long-term efficiency. In conclusion, the article argues that the adoption of AI in surgery requires an integrated approach that includes a rigorous assessment of ethical, legal and economic implications, in order to facilitate its safe and responsible implementation.

In his study [26], researcher D. Power points out that, although robotic surgery is considered safe, there is no convincing evidence to justify its preference over laparoscopic or open surgery in terms of long-term outcomes. The analysis included 50 studies, of which only four reported modest benefits in favour of robotic surgery; the remainder showed no significant differences between the techniques. Furthermore, robotic surgery has been associated with lengthy procedures and substantial costs,

limiting its adoption in low- and middle-income countries where resources are allocated to other health priorities. Power emphasises that there is a current trend towards integrating AI and automation into robotic surgery, but he also warns of the lack of robust regulatory and ethical frameworks for liability in the event of surgical errors caused by autonomous systems. The study also discusses the 'moral crumple zone' phenomenon, whereby responsibility for errors is often disproportionately attributed to the human surgeon, even when the robotic system is operating autonomously.

In conclusion, D. Power argues that there is a need to develop regulations in anticipation of the increased use of robotic technology in surgery, as well as rigorous training programmes for surgeons using robots, to ensure patient safety and clear accountability.

5. Implementation Challenges and Solutions

While the 'ethics by design' approach presents a robust framework for developing responsible medical AI robots, its implementation is not without significant challenges. These often stem from a combination of technical, organisational, and economic factors. Addressing these challenges effectively is crucial for the successful and widespread adoption of ethically designed AI systems in healthcare.

One primary technical challenge is the inherent complexity and 'black box' nature of advanced AI algorithms, particularly deep learning models. Ensuring transparency and explainability ("XAI") in these systems, as mandated by ethical principles, remains an active research area. Developers face difficulties in making algorithmic decisions fully comprehensible to human users, especially in critical medical contexts where understanding the reasoning behind an AI's suggestion is paramount for trust and accountability. Solutions include developing more interpretable AI models, integrating explainability modules that provide post-hoc explanations, and employing techniques like feature importance analysis or counterfactual explanations.

Another significant hurdle is data governance. Ethical AI development relies on high-quality, unbiased, and securely handled data. Challenges arise in collecting vast amounts of diverse medical data while ensuring patient privacy and informed consent, especially across different jurisdictions with varying data protection laws. Furthermore, historical biases present in datasets can inadvertently be perpetuated by AI systems, leading to discriminatory outcomes. Solutions include rigorous data anonymisation and pseudonymisation techniques, federated learning approaches that allow models to be trained on decentralised datasets without sharing raw data, and proactive bias detection and mitigation strategies throughout the data pipeline and model training.

Organisational challenges often revolve around the need for multidisciplinary collaboration and a shift in institutional culture. Integrating ethicists, legal experts, and sociologists into traditionally engineering-focused development teams can be difficult, requiring new communication protocols and shared understanding of objectives. Resistance to change from established practices or a lack of awareness regarding ethical implications among developers can also impede progress. Solutions involve fostering interdisciplinary training and education programmes, establishing dedicated ethical AI committees within organisations, and embedding ethical guidelines directly into project management methodologies and quality assurance processes.

Economically, implementing 'ethics by design' can incur additional costs in terms of time, resources, and specialised personnel. Developing ethically robust systems may require longer development cycles, more extensive testing, and investment in tools for ethical auditing and compliance. This can be a deterrent for companies operating under tight budgets or aggressive market timelines. To mitigate this, regulatory bodies and funding agencies could offer incentives for ethical development, and industry best practices could demonstrate the long-term cost savings associated with reduced legal risks, enhanced patient trust, and improved market reputation.

Finally, regulatory fragmentation poses a challenge. The absence of globally harmonised legal and ethical standards for medical AI robots creates a complex landscape for developers operating across different countries. Navigating diverse regulations can be costly and slow down innovation. International cooperation and the establishment of common certification pathways, drawing lessons from existing medical device regulations, are essential steps towards addressing this.

6. Future Directions and Emerging Dilemmas

The rapid evolution of AI and robotics suggests that new ethical considerations will continuously emerge, demanding proactive foresight and adaptive regulatory frameworks. As medical AI robots become more autonomous, interconnected, and integrated into daily healthcare, several future directions and potential dilemmas warrant close attention.

The increasing autonomy and cognitive capabilities of medical AI, shifting towards independent decision-making, intensify questions of moral agency and responsibility. If an AI system makes an erroneous diagnosis or performs an incorrect surgical step without human override, apportioning accountability is complex. This will exacerbate the 'moral crumple zone' phenomenon, where responsibility defaults to the human operator. Future discussions must focus on establishing mechanisms for shared responsibility (involving developers, hospitals and regulators) alongside clear legal precedents for AI-induced harm.

The rise of personalised and predictive AI in medicine also presents novel ethical challenges. While beneficial for tailored treatments, these systems rely on

extensive individual health data. The ethical implications of AI predicting disease susceptibility, life expectancy, or even behavioural tendencies, and how such predictions might influence insurance, employment, or social standing, need careful consideration. Ensuring non-discrimination and preventing the exacerbation of health inequalities, particularly for vulnerable populations, will be paramount. This necessitates robust ethical guidelines for data collection, algorithmic fairness, and the responsible communication of predictive insights.

The integration of medical AI robots with emerging technologies, such as brain-computer interfaces (BCIs), introduces profound ethical complexities, specifically regarding human identity and the "enhancement versus therapy" debate. Furthermore, the global deployment of medical AI necessitates international ethical harmonization to reconcile discrepancies in cultural values and regulatory standards across borders, a role where initiatives like the WHO guidance are vital. Finally, ethical considerations must extend to long-term societal monitoring, continuously assessing the impact on the healthcare workforce (e.g., deskilling), patient-provider dynamics, and public trust, requiring adaptive governance mechanisms for unforeseen consequences.

7. Conclusions

Against the backdrop of rapid technological progress and the growing integration of AI into robotic medical systems, this paper emphasises the urgent need for an approach rooted in robust ethical principles from the outset of the design and development process. 'Ethics by design' is not an optional extra, but a prerequisite for ensuring that technology complies with social values, fundamental human rights and professional standards. Therefore, ethical considerations must be systematically and rigorously integrated into the design process, including anticipating social consequences, protecting personal data, ensuring transparent algorithmic decision-making and providing meaningful human control over autonomous systems.

The literature review shows that ethical challenges in robotic surgery are complex, extending into legal, regulatory, and risk management spheres. Key issues like the algorithmic black box, liability for errors, and cybersecurity demand clear, tailored policies. Building legitimate frameworks requires multidisciplinary collaboration involving all stakeholders, from researchers to patients and decision-makers. Crucially, this work highlights the need for ongoing training for end-users, particularly surgeons. This training must go beyond technical aspects to include ethical, social, and legal protocols, ensuring medical staff are prepared to intervene effectively when AI system autonomy is compromised.

From a regulatory perspective, there is a significant deficit globally in standards and rules applicable to autonomous AI robotic systems, which poses significant risks to their widespread use. There is a need for international harmonization of the regulatory framework to ensure regulatory interoperability and prevent disparities that may affect the quality and safety of healthcare.

In conclusion, the 'ethics by design' approach is a fundamental pillar for the future of autonomous medical technologies. It contributes to increasing societal trust in these innovative solutions and promotes responsible technological development centred on respect for human dignity and the integrity of the medical act. Future research should focus on developing practical tools and integrated methodologies to implement ethical principles in engineering and operational processes, and on continuously monitoring the impact of these technologies in real clinical settings.

This multidimensional approach will ensure technological progress and the strengthening of a sustainable social and professional framework where innovation is balanced with accountability and transparency. This will allow the safe and ethical use of AI in medical robotics.

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