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Artificial Intelligence and Surgery: Ethical Dilemmas and Open Issues

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Running head: Artificial Intelligence, Surgery, and Ethics

Background

Artificial Intelligence (AI) applications aiming to support surgical decision-making processes are generating novel threats to ethical surgical care. To understand and address these threates, we summarize the main ethical issues that may arise from applying AI to surgery, starting from the Ethics Guidelines for Trustworthy Artificial Intelligence framework recently promoted by the European Commission.

Study Design

A modified Delphi process has been employed to achieve expert consensus.

Results

The main ethical issues that arise from applying AI to surgery, described in detail herein, relate to human agency, accountability for errors, technical robustness, privacy and data governance, transparency, diversity, non-discrimination, and fairness. It may be possible to address many of these ethical issues by expanding the breadth of surgical AI research to focus on implementation science.

The potential for AI to disrupt surgical practice suggests that formal digital health education is becoming increasingly important for surgeons and surgical trainees.

Conclusions

A multidisciplinary focus on implementation science and digital health education is desirable to balance opportunities offered by emerging AI technologies and respect for the ethical principles of a patient-centric philosophy.

Keywords: Artificial intelligence, Ethics, Surgical AI

Introduction

Artificial Intelligence (AI) is gaining importance in almost every industrial and service field, including medicine. The number of AI-related biomedical studies is rising exponentially, with almost 19,000 publications in 2020, according to a PubMed search performed in February, 2021, with keywords 'Artificial Intelligence[Title/Abstract] OR AI[Title/Abstract] OR Machine Learning[Title/Abstract]'. Also, while in 2014 only AI-based AliveCor's algorithm supporting early detection of atrial fibrillation was approved for clinical use by the FDA, 46 total algorithms were approved four years later, with radiology and cardiology profoundly involved as specialities. Today, approved AI/Machine Learning (ML)-based algorithms totalled 240 in Europe (*Conformite Europeene* – CE-marked), and 222 in the United States (Food and Drug Administration)[1].

Such algorithms can support decision-making for detection of intracranial haemorrhages or large vessel occlusions in emergent care head Computed Tomography (CT) scans, stroke and traumatic brain injuries, detection of acute findings in abdominal CT scans, liver and lung cancer diagnosis on CT and Magnetic Resonance Imaging (MRI), or X-ray wrist fracture diagnosis, among others. Intraoperatively, various computer vision models to analyze surgical videos and assist operators have been published[2]. For instance, AI to guide surgeons towards safe areas of dissection[3], segment hepatocystic anatomy and automatically assess the critical view of safety[4], and produce selective video documentation of this safety step[5] have been proposed to promote safe laparoscopic cholecystectomy.

The practice of surgery, as well as other specialities, frequently involves ethical and moral dilemmas requiring difficult choices. The spirit of AI-powered systems, at their core, is to augment the surgical decision-making processes[6]; hence nowadays, we are asking AI to augment decisions on morally and ethically challenging topics that are still blurry to humans.

With the aim of creating a framework to foster and secure ethical and robust AI, in April 2019, the High-Level Expert Group on AI of the European Commission published the Ethics Guidelines for Trustworthy Artificial Intelligence[7], stating that trustworthy AI should be lawful, namely be respecting all applicable laws and regulations, ethical, meaning compliant with the ethical principles and values, and robust from a technical perspective, but also respecting the social environment.

More specifically, according to the “Human Agency and Oversight,” AI should support human autonomy and decision-making, enabling a democratic and egalitarian society by boosting user agency, fostering fundamental rights, and always under human supervision..

Because AI-based applications should be created with a preventive approach to risks caused by the presence of other agents (human and/or artificial) that may interact with the system in a negative way, AI should ensure "Technical robustness and safety." Humans' bodily and mental integrity must be respected at the same time.

Data governance should assure the quality and integrity of the data utilized, relevance, access mechanisms, and the ability to handle data while maintaining privacy, according to the "Privacy and data governance" principle.

To enable traceability, explainability, and communication, AI should ensure "Transparency" to all essential aspects, such as data, systems, and business models.

"Diversity, non-discrimination, and fairness" represent one more value since AI should promote inclusiveness and diversity across its entire life cycle, supporting stakeholder participation, equal access through inclusive design processes, and equitable treatment.

Sustainability and ecological responsibility should be evaluated in accordance with the "Social and Environmental Well-Being" principle, as well as the UN Sustainable Development Goals (SDGs) [8].

Last but not least, AI should adhere to the "Accountability" principle, which requires proper systems to assure responsibility and accountability for AI and its consequences both before and after its development, deployment, and use.

While these guidelines represent a significant step forward, it remains unclear how they should be applied to surgical care in clinical settings.

In the light of EU Ethics Guidelines for Trustworthy Artificial Intelligence, herein we aim to find expert consensus on the main ethical issues that may arise from the application of AI-related technologies to surgery.

Methods

The Ethics Guidelines for Trustworthy Artificial Intelligence highlight seven requirements. Employing an EFTE (estimate, feedback, talk, estimate) approach[9], we gathered twelve experts in the fields of academic surgery, radiology, surgical ethics, AI and ML, computer sciences, innovation, strategy, business models, and healthcare policies to apply such requirements to surgical science and achieve consensus regarding ethical dilemmas that may arise in the application of AI in surgery. In accordance with similar studies[10–13], the selection of members was based on scouting the most recent publications on AI, their peers' recommendations, and their leadership positions across different specialities and societies. Moreover, multidisciplinarity was sought, including technology and innovation experts (from engineering, computer science, and management) with knowledge and expertise in medicine and surgery.

We used the protocol described by Nelms and Porter[9], which included the following steps:

1. Background material was provided to experts for use in formulating opinion judgments. In particular, a literature review was conducted on AI, surgery, and ethics. The initial package included The Ethics Guidelines for Trustworthy Artificial Intelligence documents.

2. Experts met in a virtual conference room. An appointed Delphi manager with expertise in both surgery and technology (JMV) encouraged dialogue among participants. To enable debate, sharing, and the generation of new knowledge, dedicated translation tools were used[14].

3. Each expert was given a Delphi questionnaire, which had to be completed and returned to the Delphi leader. Questions started from the seven requirements as defined by The Ethics Guidelines for Trustworthy Artificial Intelligence.

4. The group openly discussed the feedback results while maintaining the confidentiality of each individual's survey response.

5. Once consensus was achieved after five rounds of revisions with all the experts participating in each round, a report was generated to describe the findings. Final results were circulated among all members until everyone agreed. Results are described in the following section and reported in Table 1. The flow is shown in the following Figure 1.

Results

Human Agency and Oversight

According to the human agency and oversight requirement, AI has the goal to assist and support decision-making, which remains under human's autonomy. In doing so, AI should be beneficial to the user's organization, promoting civil rights and contributing to social equity.

The surgical literature has already highlighted how AI can support surgical decision-making[15–17], but it should not replace the surgeon's decision completely[18]. Surgeons can benefit from technology and integrate their competencies with it, depending on the situation and the needs. AI-empowered surgical robots controlled remotely could one day perform operations in hostile environments, like battlefields for wounded soldiers or long space flights[19]. More ethical concerns arise when AI-powered surgical robots exercise some degree of autonomy, either being autonomous for specific tasks (level 2), proposing strategies to be validated (level 3), carrying out the decision-making process (level 4), or achieving full autonomy (level 5)[20].

Therefore, it is essential to generate the best human-machine interface and combination according to the specific situation, safeguarding human agency and oversight.

In such a perspective, issues connected to surgeons' non-technical or "soft" skills emerge. Such skills have proved to be crucial in surgical teamwork, especially in complex contexts like trauma and emergency surgery[21,22] and during challenging times like the recent COVID-19 pandemic[23,24]. Among such skills, creativity stands as essential for surgeons[25,26]. Still, contemporary machines do not seem to have those soft-skills abilities that characterize surgical leaders[27].

Technical Robustness and Safety

According to the technical robustness and safety principle, AI should be reliable and developed with a preventive approach to risks caused by the interaction of other agents, both human and artificial. Should agents interact with the system in an adversarial manner, the physical and mental integrity of humans must be prioritized.

The first ethical issue arises in model training. In a continual learning framework, if the training data are robust and the algorithm is appropriate, as time passes, the algorithm becomes more precise and accurate. Therefore, those surgeons and patients who use the early and less educated versions of the model may receive suboptimal decision support, conferring a sort of "guinea pigs" risk[28].

Even if algorithms are disclosed with full transparency, when patients and surgeons rely on AI predictions, many times, the reason and calculations to generate the output of a model cannot be explained, the gist of the "Black Box" issue[29]. In fact, even models achieving high prediction accuracies cannot often explain a priori the influence of features and, even more importantly, predict instances or populations where the model is likely going to fail. Therefore explainable AI (XAI) is essential to optimize transparency, define clear indications for the use of models, and build trust among patients, surgeons, and regulators. The principle of nonmaleficence (avoiding harm to patients) applies when training does not accurately represent patients and situations in which the algorithm is applied. The risk of low quality or poor data entry (for instance, when data used to train the algorithm is poor in terms of quality, e.g., using suboptimal videos performed by less trained surgeons, or in another layer, videos poorly annotated or annotated without optimal criteria) may generate low-quality outcomes (so-called “garbage in, garbage out” rule)[29], leading to potentially harming patients or providing them and clinicians with inadequate decision-making aids.

Technology enthusiasts claim that AI can solve several biases, mistakes, and problems. This may be true when algorithms are trained exclusively on objective features derived from diverse and balanced training cohorts. However, AI does not consider the human effect. In fact, AI-based applications are most often trained on bias data, both due to a selection bias and subtoptimal annotations, with the risk of amplyfing such issues. In addition, ethical concerns were illustrated in the movie “Sully”[30], in which the pilot’s integrity was interpreted through the employment of simulation models. Everything looked perfect using the software, but the system did not consider human physiological constraints or realistic uncertainty.

Moreover, AI suffers from the so-called “stupidity”[31] problems. AI systems can be fooled in ways that humans cannot, and AI mistakes are less predictable[32]. For instance, artificially inserting a random object in an image alters the performance of AI-based object detectors on the whole image, not only the replaced object[33].

Technical robustness requires the need to link AI with other technologies (like cyber security systems) to protect its security. Ensuring cybersecurity and cyber resilience stands as a maximum priority[19].

<u>*Privacy and data governance*</u>

AI impacts privacy. Data governance should ensure the quality and integrity of the data used, its relevance, its access protocols, and the capability to process data while protecting privacy.

Data is the most valuable item in training data-hungry AI algorithms. Ethical issues related to sensitive patient data governance arise, and they are closely connected to modern ethical approaches to patient data. One dilemma concerns the transfer of data from the hospital to the manufacturer. In several countries, most hospitals are public organizations funded by citizens. The inherent risk is that data is transferred for free to private entities (i.e., manufacturers). Once public entities purchase new surgical equipment, they will pay for something created starting from the data they generated. The business model risks are very similar to what happens in the research publication field, in which scholars produce knowledge while being paid by their institutions, which cannot access such published knowledge unless they pay a subscription or open access fees.

Transparency

Transparency must be granted to AI training data, algorithms, and business models to ensure traceability, explainability, and open communication.

Once relying on AI support in surgical decision-making, clinicians must be aware of the current state-of-the-art performance of AI models, especially in preventive medicine. Once surgeons use an AI-based tool, they should be aware of the motivations and state of data of the algorithm they are employing at the moment of the evaluation. Indeed, users should be aware of the indication and setting for optimal deployment, as variability in the target population (data shifts) and/or data acquisition (e.g. recording equipment) might hamper performance. Before deploying an AI-based tool in clinical practices, surgeons should evaluate the fitness of the model for his/her set of patients. To this end, transparent reporting of data used during models development would allow identification of eventual domain shifts between the patients' population used during training and testing of the AI and the patients' population of interest. Furthermore, publishing protocols used for annotating training and testing data could favour reproducibility and help building trust around the performance of AI[34].

Diversity, non-discrimination, and fairness

According to the diversity, non-discrimination, and fairness requirement, AI should enable inclusion and diversity throughout its entire life cycle, ensuring stakeholders' participation, equal access through inclusive design processes, and equal treatment.

Peer-reviewed literature has highlighted the danger of discrimination cases concerning gender and race due to biased data[35]. In particular, the use of Deep Neural Network algorithms, does not consent explicability and may inherit bias from data, which are later translated into biased information which affect decision-making. This stands as an open topic for all the interdisciplinary scientific communities engaged in AI development[36]. A specific communication of the Council of Europe stated that the most relevant, existing legal tools to mitigate the risks of AI-driven discrimination are non-discrimination and data protection laws[37]. Also, AI opens the door to new types of discrimination that escapes these laws. For example, model overfitting can cause erroneous predictions leading to poor decisions.

Moreover, AI can be expensive. The cost and accessibility of AI-based devices and training data could disproportionately hinder developing countries, exacerbating the topic of surgical disparities and, most specifically, the so-called provider-related factors and clinical care and quality[38]. A general call emerges to find practical solutions to ensure equity in surgical care, also leveraging on the availability of data, technology, and clinical education, not to let the poorest behind[39]. Technology can support bridging the gap[24,40,41], but also enlarging it if not used properly[42].

AI relies on data, and technology can create wealth through data availability. Connecting to the goal of fostering social equity, an ethical dilemma arises: should those who generate such data (e.g., the patients) be compensated financially? Interventions are expensive, no matter if the operation is billed to the patient, the health insurance, or incurred by a National Health System. Manufacturers can use data generated during surgery to create and profit from higherperforming surgical instruments. Still, no reimbursement will be granted to those who paid for the operation.

Moreover, machines do not take into consideration the tailored approach to the patient, namely the patient's preferences and background, family's wishes, cultural and religious regards, and emotional and ethical implications[29,43]. In theory, a well-trained algorithm will always recommend the best clinical solution, for instance, prescribing glossectomy for an individual with tongue cancer no matter if the patient is a chef or a culinary expert who values the quality of life provided by the sense of taste[29]. Therefore, patient-surgeon synergies[18], shared-decision making[29,44], and co-production dynamics[45,46] can be more challenging when machine interaction is involved, as only the most convenient clinical choice will be taken into account, regardless of the patient's preferences.

Societal and environmental well-being

According to the United Nations Sustainable Development Goals[47], AI should encourage sustainability and ecological responsibility.

Ethical concerns about clinical knowledge transfer and medical education arise. Even though AI could be used to foster surgical education[48], many clinical disciplines, such as radiology, are poised to change profoundly, as do the tasks performed by medical doctors. Understanding what AI can do better than humans, and the future clinical applications should be reflected in educational curricula for doctors-to-be, as well as for training surgeons in their life-long learning education, ensuring adequate knowledge transfer and knowledge translation mechanisms[14].

There is a need to rethink the new surgeons' skillset, understanding the new technical and non-technical skills, which may differ from the current ones and across specialities[43].

Healthcare professionals skilled in the domain of AI/ML are needed to lead the deployment and adaptation of AI-based tools into clinical scenarios, securing their implementation as well as its surveillance over time. Moreover, AI may change the role of other professionals working with surgeons, e.g., anesthesiologists. New paradigms in education also involve other clinicians[27].

Another fascinating issue related to education is whether ethics can be taught to AI-empowered robots. While ethical dilemmas rarely lead to only one answer, ethical reasoning can rely on critical decision trees. It may be useful to represent ethical reasoning in a learning model.

Accountability

According to the accountability requirement, adequate mechanisms should be put in place to ensure responsibility and accountability for the use of AI and its outcomes, both before and after its development, deployment, and use.

Ethical concerns arise in the measurement of surgical outcomes. Liability issues emerge, with the need to understand who should be blamed or rewarded for the surgical outcome and to what extent: the surgeon/operator, the manufacturer, those in charge of algorithm maintenance[19], hospital authorities, data owners, or a combination thereof. New regulations should establish precedents for handling such cases.

Results are summarized in the following Table 1.

Discussion

AI is evolving from being a futuristic promise into a reliable and helpful tool for clinical use. AI-based devices have been proposed and approved in several disciplines – though not yet in surgery – to assist rote, repetitive tasks. Rapid technology development may further expand clinical AI applications, disrupting traditional clinical practices. Therefore, surgeons should be familiar with its potential for both benefit and harm. Although the technical aspects may remain unknown to the most, the practical and ethical consequences will need to be addressed. For example, AI is challenging core ideas of the philosophical framework of human agency. Ethical dilemmas should be addressed in the early phases of technology design, development, and adoption. AI algorithms must be developed and implemented with the highest safety, privacy, transparency, and accountability standards, as required by many international digital ethics experts and prominent public bodies like the European Commission with its Ethics Guidelines for Trustworthy Artificial Intelligence. In addition, other questions should be answered to reach lawful, ethical, and robust solutions: should we ask AI to address issues that remain controversial to humans? If yes, should we ask AI to approach these issues in a human-centered manner, as we do?

AI could enable inclusion and diversity, ensuring equal access through inclusive design processes and equal treatment; what technical mechanisms and process design should be implemented to avoid discrimination and empower the ability to AI to contribute to a more inclusive society and equitable access to healthcare? Even when following the existing laws and best practices, diversity, equity, non-discrimination, and fairness cannot be ensured a priori, and AI-specific risks can arise.

Conclusions

Our paper highlights some open topics and dilemmas to offer a framework for ongoing debates to deepen and share knowledge to contribute to a more digital-aware surgical community. As AI may disrupt surgery soon, digital education is becoming increasingly important for surgeons and surgical trainees. A multidisciplinary perspective, including surgeons, scientists, developers, and policymakers, should be employed to address the open issues, ensuring the right balance between the unique advantages and opportunities offered by the new technologies and the respect for the ethical principles of a patient-centric perspective. To accomplish this, we propose expanding the field of our research to include implementation science applications and foster dialogue across stakeholders.

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Figure legends

Figure 1. The estimate, feedback, talk, estimate (EFTE) process. AI, artificial intelligence.

Precis

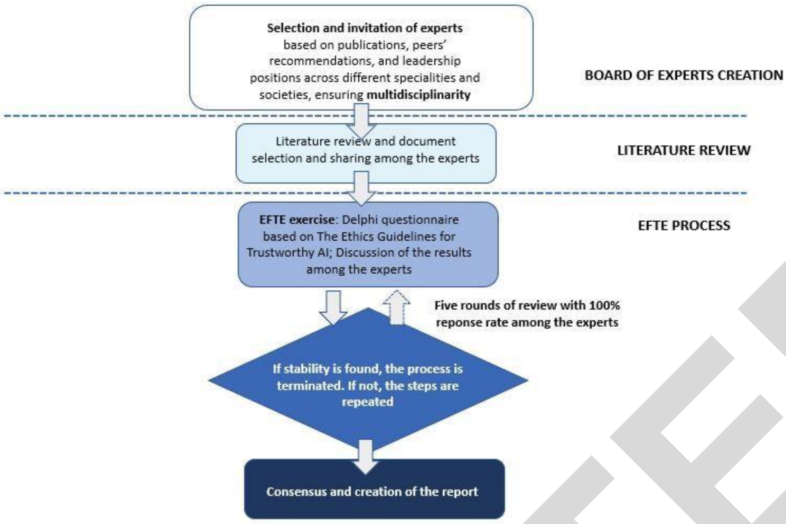
Artificial intelligence (AI) supports surgical decision-making. Employing a Delphi methodology, our study summarizes the main ethical issues that arise from applying AI to surgery, starting from the European Union Ethics Guidelines for Trustworthy Artificial Intelligence framework. Results lead to some open questions to be investigated by the surgical community.

Table 1. Results

Requirement	Definition	Topics from the surgical practice
Human agency and oversight	AI should support human autonomy and decision-making. AI should act as an enabler to a democratic and equitable society by supporting the user's agency, foster fundamental rights, and allow for human oversight.	Surgical decision-making; optimal human-machine interface; non-technical skills and creativity
Technical robustness and safety	AI should be reliable and developed with a preventive approach to risk caused by the presence of other agents (human and artificial) that may interact with the system in an adversarial manner, ensuring at the same time the physical and mental integrity of humans.	Monitoring continual learning AI; explainability of models performance; optimal integration in surgical workflows; artificial stupidity, cyber security and cyber resilience
Privacy and data governance	AI can impact privacy. Data governance should ensure the quality and integrity of the data used, its relevance, its access protocols, and the capability to process data protecting the privacy.	Sensitive data, consenting and data ownership; business model in data management
Transparency	Transparency must be granted to the elements relevant to AI, like the data, the system, and the business models, ensuring traceability, explainability, and communication.	Accurate reporting of training data and models performance
Diversity, non-discrimination, and fairness	AI should enable inclusion and diversity throughout its entire life cycle, ensuring stakeholders' participation, with equal access through inclusive design processes as well as equal treatment.	Access to diverse and representative surgical data; access to the technology from developing countries; potential rewards of data availability; shared decision-making, co-production, and tailored approaches dynamics
Societal and environmental well-being	Other sentient beings and the environment represent stakeholders throughout the AI's life cycle, encouraging sustainability and ecological responsibility, also according to the SDGs.	Surgical education and knowledge transfer; surgical skillset
Accountability	Adequate mechanisms should be put in place to ensure responsibility and accountability for AI and its outcomes, both before and after their development, deployment, and use.	Measurement; liabilities and rewards

AI, artificial intelligence; SDG, sustainable development goals

Figure 1



Selection and invitation of experts based on publications, peers' recommendations, and leadership positions across different specialities and societies, ensuring multidisciplinarity
BOARD OF EXPERTS CREATION
Literature review and document selection and sharing among the experts
LITERATURE REVIEW
EFTE exercise: Delphi questionnaire based on The Ethics Guidelines for Trustworthy AI; Discussion of the results among the experts
EFTE PROCESS
Five rounds of review with 100% reponse rate among the experts
If stability is found, the process is terminated. If not, the steps are repeated
Consensus and creation of the report