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Title "Ethics and Trustworthiness of Artificial Intelligence in Clinical Surgery "

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## "Ethics and Trustworthiness of Artificial Intelligence in Clinical Surgery "

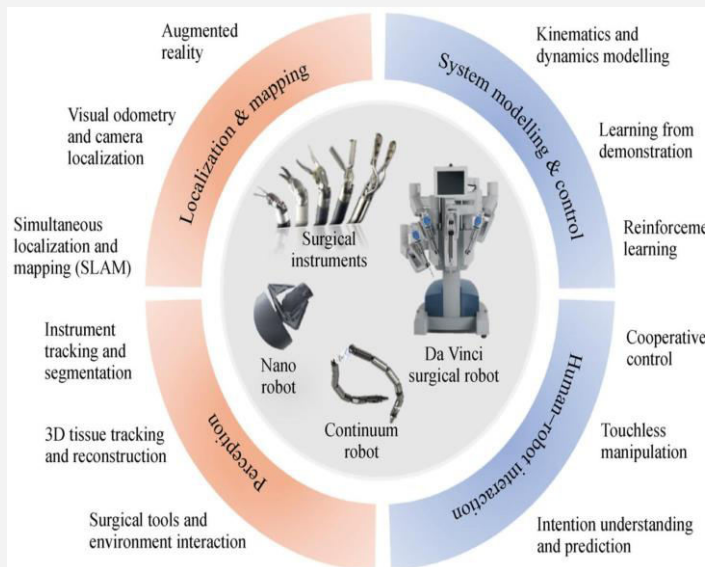
Prof. R.V. Deshmukh<sup>1</sup>, Prathamesh Kawale<sup>2</sup>, Pratham Wadhvani<sup>2</sup>, Prathamesh Waghchore<sup>3</sup>, Pratik Dhale<sup>4</sup>.

### Abstract:

This white paper documents the consensus opinion of the Artificial Intelligence Surgery (AIS) task force on Artificial Intelligence (AI) Ethics on the ethical considerations and current trustworthiness of artificial intelligence and autonomous actions in surgery. The ethics were divided into 6 topics defined by the Task Force: Reliability of robotic and AI systems; Respect for privacy and sensitive data; Use of complete and representative (ie., unbiased) data: Transparencies and uncertainties in AI; Fairness: are we exacerbating inequalities in access to healthcare?: Technology as an equalizer in surgical education. The ethical framework of ethical values-ethical principles-ethical norms is used to propose corresponding ethical governance countermeasures for trustworthy medical AI from the ethical, legal, and regulatory aspects. The involvement of medical AI in clinical practices may threaten doctors 'and patients' autonomy and dignity. When accidents occur with medical AI, the responsibility attribution is not clear. All these factors affect people's trust in medical AI. At the legal level, current medical AI does not have moral status and humans remain the duty bearers. At the regulatory level, strengthening data quality management, improving algorithm transparency and traceability to reduce algorithm bias, and regulating and reviewing the whole process of the AI industry to control risks are proposed. In order to make medical AI trustworthy, at the ethical level, the ethical value orientation of promoting human health should first and foremost be considered as the top-level design.

**Keywords:** Algorithms; Artificial intelligence; Data; Ethics; Governance; Healthcare; Regulation; Responsibility attribution.

### INTRODUCTION



Ethics and trustworthiness are essential considerations when it comes to the use of Artificial Intelligence (AI) in medical surgery. AI has the potential to significantly improve surgical outcomes by enhancing precision,

efficiency, and patient care. However, it also raises important ethical and trust-related concerns that need to be addressed.

Firstly, the ethical implications of using AI in surgery revolve around issues such as transparency, accountability, and fairness. Surgeons and healthcare professionals must understand the AI algorithms used, ensure that they are unbiased and based on valid data, and be able to explain their decisions to patients. Lack of awareness or understanding of the AI systems may lead to mistrust and skepticism among patients, compromising their autonomy and informed consent. Additionally, the reliance on AI in surgical decision-making raises concerns about liability and accountability. Establishing clear guidelines and regulations around AI in surgery is crucial to ensure accountability and protect patient safety. To enhance trustworthiness, ethical considerations surrounding data privacy and security are paramount. Protecting patient's personal information and ensuring secure data

transfer and storage is necessary to mitigate any potential breach or misuse of sensitive data. Maintaining patient confidentiality and adhering to ethical guidelines are essential to sustain trust in AI technology.

Ethics in AI refers to the moral principles and guidelines that govern the development, deployment, and use of AI technologies. In the field of medical surgery, these ethical considerations become even more critical as they directly impact patient safety, privacy, and overall healthcare quality. Some key ethical concerns related to AI in medical surgery include:

**1. Patient Autonomy and Informed Consent :** The use of AI in medical surgery may involve complex algorithms and decision-making processes that patients might not fully understand. It becomes crucial to ensure that patients are well-informed about the involvement of AI in their treatment and provide informed consent.

**2. Transparency and Explainability:** AI systems can be highly intricate, making it challenging for healthcare professionals and patients to understand how they arrive at certain decisions. Ensuring transparency and explainability in AI algorithms is crucial to building trust and enabling medical professionals to validate the AI's recommendations.

**3. Bias and Fairness:** AI algorithms learn from data, and if the data used to train them contain biases, the AI system can perpetuate these biases, leading to inequitable treatment. It is vital to address bias in AI models to ensure fair and unbiased healthcare delivery.

**4. Data Privacy and Security:** AI systems rely on vast amounts of patient data for training and decision-making. Safeguarding patient data privacy and ensuring robust security measures are in place to prevent unauthorized access are critical considerations.

**5. Accountability and Liability:** Determining responsibility in case of AI-related errors or adverse outcomes can be challenging. Clarifying who is accountable for AI decisions is essential to establish accountability and liability frameworks.

**6. Human-Machine Collaboration:** AI should be viewed as a tool to augment human capabilities rather than replace human expertise. Ensuring effective collaboration between AI and healthcare professionals is essential for successful and ethical integration.

## Methods

Surgery is defined as all interventional medical disciplines, including surgery, endoscopy, and interventional fields such as interventional radiology and cardiology. AI in surgery is defined as the use of ad-hoc algorithms involved in learning procedures for prediction and/or classification in the pre-operative and post-operative phases. Artificial Intelligence Surgery (AIS) is defined as the utilization of such algorithms during an actual intervention and covers autonomous actions during a procedure. We adopted a multidisciplinary approach and summarized five subjects that influence the trustworthiness of medical AI: data quality, algorithmic bias, opacity, safety and security, and responsibility attribution, and discussed these factors from the perspectives of technology, law, and healthcare stakeholders and institutions. The ethical framework of ethical values-ethical principles-ethical norms is used to propose corresponding ethical governance countermeasures for trustworthy medical AI from the ethical, legal, and regulatory aspects.

## Results

### 1. Reliability of robotics and AI systems

Reliability in robotics and AI systems refers to the ability of these systems to perform their intended tasks consistently and accurately over time, without unexpected failures or errors. The reliability of robotics and AI systems can vary depending on a number of factors, including the complexity of the system, the quality of the hardware and software components, and the level of testing and validation that has been conducted. In general, robotics and AI systems have the potential to greatly improve reliability compared to human-operated systems. They can perform repetitive tasks with high accuracy and precision, without being affected by factors. Additionally, AI algorithms can analyze large amounts of data and make decisions based on patterns and trends, potentially reducing human error.

However, there are also challenges and limitations that can impact the reliability of robotics and AI systems. Hardware failures, software bugs, or communication issues can lead to system malfunctions and unexpected behavior. Furthermore, AI algorithms can sometimes be influenced by incomplete data, leading to incorrect decisions or predictions. To mitigate these reliability challenges, extensive testing and validation processes



are necessary. This involves simulating various scenarios and edge cases to ensure the system performs reliably under different conditions. Additionally, continuous monitoring and maintenance are required to identify and resolve issues that may arise during operation.

Here are some key aspects and considerations related to the reliability of robotics and AI systems:

- **Design and Development:** The design phase is critical for ensuring reliability. Developers need to thoroughly understand the requirements and constraints of the system, consider potential failure modes, and design mechanisms to detect and mitigate these failures.
- **Testing and Validation:** Testing and validation procedures are essential to identify and correct potential issues before deployment. This includes simulated testing, real-world testing, and stress testing under various conditions.
- **Redundancy:** Incorporating redundancy in critical components or functions can enhance reliability. Redundant systems provide backup mechanisms in case of primary system failures, minimizing downtime and ensuring continuous operation.
- **Sensing and Perception:** For robotics and AI systems to operate reliably, they need accurate and robust sensing and perception capabilities. Sensor fusion techniques, machine learning algorithms, and sensor redundancy can help improve the accuracy and reliability of perception systems.
- **Adaptability and Resilience:** Designing systems that can adapt to changing environments and handle unexpected situations is crucial. AI algorithms that can handle novel scenarios and adjust their behavior based on new information contribute to overall system reliability.
- **Human-Machine Interaction:** Ensuring effective communication and collaboration between humans and AI systems is important for reliability. Systems should be designed to seek human assistance when facing uncertain situations they can't handle autonomously.
- **Fail-Safe Mechanisms:** Incorporating fail-safe mechanisms can help mitigate the impact of failures. These mechanisms might involve stopping the system, reverting to a safe state, or notifying operators of the issue.

- **Cybersecurity:** Robust cybersecurity practices are essential to protect AI and robotic systems from hacking, unauthorized access, and malicious manipulation, which can compromise their reliability and safety.
- **Maintenance and Monitoring:** Regular maintenance and monitoring of robotic and AI systems are necessary to identify wear and tear, potential hardware or software degradation, and other issues that could affect reliability.
- **Regulations and Standards:** Adherence to industry standards and regulations related to safety and reliability is crucial, especially in domains where these technologies can have significant societal impacts.
- **Continuous Improvement:** Reliability should be an ongoing focus. Collecting data on system behavior, analyzing failures, and implementing improvements based on lessons learned contribute to the long-term reliability of the system.
- **Ethics and Transparency:** Ensuring that AI systems behave ethically and transparently contributes to their reliability. Users should have a clear understanding of how the system operates and makes decisions.

## 2. Respect for privacy and sensitive data

Respecting patient privacy is a fundamental ethical principle in healthcare. As we deploy AI systems, it is crucial to ensure that patient information is handled with care and that it remains confidential and secure. Respect for privacy and sensitive data in healthcare is most important when implementing artificial intelligence (AI) systems. AI technologies have the potential to revolutionize healthcare by enabling advanced and efficient diagnosis, treatment, and research. However, to fully realize these benefits, it is crucial to prioritize and protect patient privacy and confidentiality. Healthcare organizations and AI developers should ensure that patient data is handled with the highest level of security and privacy. This includes abiding by relevant laws and regulations regarding data protection, such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States or the General Data Protection Regulation (GDPR) in the European Union. AI systems should be designed to encrypt and store data securely, restrict access only to authorized personnel,

and implement measures to prevent unauthorized data breaches.

Healthcare providers should obtain informed consent from patients before involving their data in AI systems. Patients should have a clear understanding of how their data will be used, the purpose of the AI system, and any potential risks or benefits involved. Transparent and easily understandable consent forms and processes should be established, ensuring patients can make informed decisions about the usage of their data. To respect privacy, healthcare organizations and AI developers should adopt data minimization principles. Only the necessary and relevant data should be collected, and any unnecessary identifiers should be removed. Use of de-identified data sets can help strike a balance between facilitating research and preserving patient privacy. Here are some key principles about Patients privacy :

- **Anonymization and De-identification:** AI algorithms should be designed to work with anonymized or de-identified data whenever possible. By removing personal identifiers, we can protect patient identities while still benefiting from large datasets for training AI models.
- **Limited Data Access:** Only authorized personnel should have access to patient data, and access should be limited to what is necessary for their specific roles.
- **Sensitive Data Protection:** Healthcare data often contains sensitive information about patients, including medical conditions, genetic data, and treatment histories. Protecting this sensitive data is not only a legal requirement but also a moral obligation.
- **Secure Data Storage:** AI systems should store data in highly secure environments, such as encrypted databases and protected servers, with rigorous monitoring for potential breaches.
- **Transparent Communication:** Healthcare providers and AI developers should communicate transparently with patients about the benefits, risks, and potential impact of AI technologies on their care.
- **Regular Auditing and Monitoring:** Regular auditing and monitoring of AI systems are essential to detect and address any potential privacy breaches or data misuse.

- **Continuous Evaluation:** AI systems should undergo regular evaluations to ensure they comply with privacy regulations and maintain a high standard of data protection.

By adhering to these principles and practices, we can foster trust between patients, healthcare providers, and AI developers.

The benefit of AI systems in clinical surgery is that AI systems can provide real-time analysis and decision support during surgical procedures, which can help improve surgical precision. This can be particularly helpful in delicate and complex surgeries. AI systems can assist surgeons in minimizing human errors during surgery. By providing data-driven insights and assisting in decision-making, they can help reduce the chances of mistakes or complications. It can analyze vast amounts of patient data, including medical images and patient records, to aid in diagnostics and treatment planning. They can provide accurate and faster analysis than humans and assist in identifying abnormalities or potential risks. It can analyze individual patient data to provide personalized care plans. This includes predicting treatment outcomes, suggesting personalized rehabilitation plans, or providing personalized drug dosage recommendations. It can continuously monitor patients during surgery and provide real-time feedback to the surgeon. They can alert the surgeon to any changes or potential issues, enabling quick response and intervention. By automating certain tasks and reducing the need for manual analysis, AI systems can save time and cost in surgical procedures. This can free up the surgeon's time for more critical tasks and improve overall healthcare efficiency.

In the future, the promise of improved healthcare for the global community through the use of AI ecosystem assets will be recognized and will continue to result in increased outcomes. The use of AI requires access to a wide range of data residing in disparate information systems and involves data transformation and analysis at many levels. This complexity creates significant challenges in ensuring not only the privacy of patient data but also the governance of its intended use. It is imperative that healthcare organizations, vendors, regulators, policymakers, patient advocates, and all

other relevant third parties work together to further develop policies and procedures that mitigate the risk of data misuse while enabling innovation driven by advances in AI use. The future scope of AI in healthcare holds great potential to revolutionize the industry. Here are some areas where AI can have a significant impact:

- **Diagnosis and Treatment:** AI algorithms can analyze large amounts of patient data, including medical records, test results, and imaging scans, to assist in accurate and timely diagnosis. It can also provide treatment recommendations based on the best available evidence and personalized patient profiles.
- **Drug Development:** AI can speed up the process of drug discovery and development by analyzing large datasets, identifying potential drug candidates, predicting their efficacy and side effects, and designing clinical trials. This can potentially reduce costs and time associated with bringing new drugs to market.
- **Healthcare Operations:** AI can optimize healthcare operations by streamlining administrative tasks, automating routine processes, and improving resource utilization. This can free up healthcare professionals' time, enhance efficiency, and improve overall patient care.
- **Mental Health Support:** AI-based chatbots and virtual assistants can provide round-the-clock support to individuals dealing with mental health issues. They can offer personalized advice, monitor symptoms, and connect patients to appropriate resources when necessary.
- **Robot-Assisted Surgery:** AI-enabled robots can support surgeons during complex procedures, offering greater precision, accuracy, and better patient outcomes. These robots can analyze real-time data, detect anomalies, and provide real-time guidance during surgery.

In the pre-AI environment that healthcare experienced as it transitioned from an entirely analog to an increasingly digital delivery model, the privacy and security challenges were complex but manageable. Data de-identification of direct identifiers (e.g., name and biometrics) and indirect identifiers (e.g., race, religion, and age) was accomplished using a variety of

tools and techniques, including the use of algorithms. The challenge of data de-identification has been, and remains, the risk of re-identification, which increases with the use of both direct and indirect identifiers. Although there has been considerable experimentation with the use of AI in healthcare over the last 50 years, the last 10 years have seen an explosion in the development of software for healthcare applications, fueled by the growth and availability of extremely powerful computing resources and other related services provided by various cloud providers such as Microsoft, Google, and Amazon. The promise of AI outcomes in healthcare, including early disease diagnosis, tailored cancer treatment protocols, disease risk factor detection, mental health insights, and many others, requires access to vast pools of objective and subjective data residing in a plethora of information systems not limited to electronic medical records (EMRs).

### 3. Use of complete and representative data

AI is a technology designed by humans to replicate, augment or replace human intelligence. These tools typically rely on large amounts of data to generate insights. Poorly designed projects based on biased data can have unintended, potentially harmful consequences. Moreover, the rapid advancement of algorithmic systems means that in some cases, it is not clear how AI reached its conclusions, so we are essentially relying on systems that we cannot explain to make decisions that could affect society. The word "biased" means unfairly prejudiced for or against someone or something [15], usually reflecting widespread societal biases. The EU Charter of Fundamental Rights lists the following characteristics as morally relevant in cases of discrimination: sex, race, color, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age and sexual orientation. The use of complete and representative data is crucial in healthcare when utilizing AI systems for several reasons:

**a. Accuracy and Reliability:** Complete and representative data ensures the accuracy and reliability of AI models and systems. Without complete and representative data, the AI system may miss important



patterns or exhibit biased behavior, leading to incorrect diagnoses or treatment recommendations.

**b. Generalizability:** Complete and representative data allows AI systems to generalize well to real-world scenarios. Healthcare data can be complex and highly variable, with numerous factors influencing patient outcomes. This generalizability enhances the utility and effectiveness of AI systems in real healthcare settings.

**c. Avoiding Bias and Disparities:** Complete and representative data helps mitigate bias and disparities in healthcare. Incomplete datasets may accidentally perpetuate inequalities in access to healthcare, diagnosis accuracy, or treatment outcomes. AI systems trained on representative data are better equipped to provide fair and equitable healthcare decisions, irrespective of factors such as race, gender, age.

**d. Identification of Rare or Uncommon Cases:** Complete data that includes a wide range of patient profiles and medical conditions ensures that AI systems can effectively identify rare or uncommon cases. By training on diverse data, AI models can recognize patterns associated with rare diseases, atypical symptoms, or unique patient characteristics.

**e. Safety and Liability:** Utilizing complete and representative data is crucial from a safety and liability perspective in healthcare. Complete data contributes to improved system performance, minimizing the potential for errors and ensuring patient safety.

**f. Ethical Considerations:** The use of complete and representative data aligns with ethical considerations in healthcare. It promotes fairness, transparency, and patient-centered care. By incorporating diverse patient data, AI systems can foster a deeper understanding of various health disparities, social determinants of health, and individual patient needs.

**g. Trust and Acceptance:** In healthcare, trust in AI systems is paramount. Patients, clinicians, and other stakeholders are more likely to trust AI-generated recommendations when they know the underlying data is comprehensive and representative.

**h. Reducing Errors and Misdiagnosis:** AI systems are used to assist healthcare professionals in diagnosing diseases and planning treatments. Having access to complete and representative data enhances the accuracy of the AI system, reducing the risk of errors and misdiagnoses

#### **i. Research and Continuous Improvement:**

Complete and representative data is essential for research purposes and ongoing improvement of AI models. Accurate data helps researchers and developers identify shortcomings and make necessary enhancements to the system.

#### **4. Transparencies and uncertainties in AI**

Transparencies and uncertainties in AI The development, deployment, and use of reliable AI in surgery require a transparent approach to both the opacity of AI algorithms and the uncertainties associated with using these types of techniques as decision- support tools in clinical settings As the computational complexity of AI algorithms and predictions increases, it becomes difficult for humans to understand and explain why a model has produced a particular output or arrived at a particular clinical decision. This is known as the "black box effect". The opacity of the process raises ethical issues. In the field of healthcare, AI brings both transparencies and uncertainties. Let's explore these aspects:

##### **Transparency:**

- **Explainability:** AI algorithms in healthcare should aim to provide clear explanations for their recommendations or decisions. Transparency is crucial for establishing trust and user acceptance, especially when dealing with sensitive healthcare data and critical healthcare decisions.
- **Data Transparency:** Transparency related to data usage is crucial in healthcare AI. It involves making patients aware of how their data is collected, stored, shared, and used by AI systems, ensuring transparency and patient consent in data handling processes.

##### **Uncertainties:**

- **Data Quality:** AI models heavily rely on data quality and quantity. Uncertainties may arise if the datasets used to train the AI models are incomplete, biased, or unrepresentative of the larger population. These issues can lead to inaccurate predictions or decisions.
- **Liability and Accountability:** Uncertainties may arise regarding liability and accountability when AI systems are involved in healthcare decisions. Who is responsible for potential errors or adverse outcomes? Clear policies and guidelines need to be

established to address the legal, ethical, and responsibility aspects of AI deployment in healthcare.

It is essential to navigate these transparencies and uncertainties in healthcare AI by promoting transparency, ensuring interpretability, addressing biases, addressing privacy concerns, and establishing accountability frameworks. By addressing these challenges, AI can contribute positively to healthcare outcomes while upholding transparency, fairness, and ethical considerations.

## 5. Ai technology as equalizer in surgical training

AI technology can serve as an equalizer in surgical training by providing accessible and personalized learning opportunities for aspiring surgeons. Traditionally, surgical training has relied on limited opportunities for hands-on experience, which can create disparities in skill development among trainees. However, AI can bridge this gap by offering virtual simulations and training modules that can be accessed anytime and anywhere. With AI, trainees can practice surgical procedures in a safe and controlled environment, allowing them to gain experience and refine their skills without the risk of harming patients. AI algorithms can analyze trainees' performance in real-time, providing immediate feedback and guidance for improvement. This personalized approach helps each trainee focus on their specific areas of weakness, enhancing their overall competence and confidence. Furthermore, AI technology can capture and analyze data from surgical procedures, enabling trainees to review their own performances and learn from their mistakes. This data-driven feedback loop can accelerate the learning process and facilitate continuous improvement. By democratizing access to surgical training through AI, aspiring surgeons from all backgrounds can have equal opportunities to develop their skills and expertise. This not only promotes a more inclusive and diverse surgical workforce but also enhances patient safety by ensuring that surgeons are well-prepared and competent.

## Conclusions

In conclusion, ethics and trustworthiness are critical considerations when it comes to AI systems in clinical surgery. Firstly, ethical concerns arise due to the potential impact of AI on patient safety and well-

being. It is essential to ensure that AI systems are developed and implemented with a focus on patient-centric care, prioritizing the best interests of the individual. This includes maintaining privacy and confidentiality of patient data, obtaining informed consent, and ensuring transparency in the decision-making process of AI algorithms. Trustworthiness is crucial for AI systems to gain acceptance and adoption in clinical surgery. Surgeons and patients need to have confidence in the accuracy, reliability, and effectiveness of AI technologies. This requires rigorous testing, validation, and continuous monitoring of AI systems to ensure their performance aligns with established standards and guidelines. Additionally, explainability and interpretability of AI algorithms are important for surgeons to understand the reasoning behind recommendations or decisions made by the system. We are at the dawn of a new technological revolution that has the potential to dramatically change the way healthcare is delivered. Unlike previous periods of innovation in medicine, many of the innovations are being developed by non-medical people because the number of doctors with expertise in computer science and AI is limited. To enhance ethics and trustworthiness, collaboration between clinicians, AI developers, regulatory bodies, and other stakeholders is essential. Establishing clear guidelines and regulations for the development, deployment, and use of AI systems in clinical surgery can help address ethical concerns and ensure trustworthiness. Ongoing education and training for surgeons on the capabilities and limitations of AI technologies are also crucial to foster trust and enable effective collaboration between human surgeons and AI systems. One of the reasons we started this journal is to help organize the physicians who are interested in this topic and to disseminate the concepts in a form that all modern surgeons can understand and digest. As economic inequalities continue to grow globally and within countries, the potential for AI to fill gaps and improve access to healthcare must be tempered by the potential for these technologies to be misused and ultimately exacerbates inequalities in healthcare delivery and access. The complexity of ML algorithms has created such a "black box" effect that it could be argued that all surgical departments already need a dedicated member of their team to accurately and safely integrate AI into patient care.



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