

EDITORIAL

Ethics and Legal Framework for Trustworthy Artificial Intelligence in Vascular Surgery

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Artificial Intelligence (AI) has the potential to improve care for patients with vascular diseases through various applications to enhance the screening, detection, evaluation of prognosis, decision making, and planning of therapeutic interventions.^{1–3} While the digital transformation of healthcare brings new opportunities for medical and surgical practice, clinical research, and education, it also raises major social and ethical concerns regarding responsibility and accountability, with legal frameworks currently being developed. Here, the main ethical challenges raised by AI are highlighted and an overview of the main regulations currently being developed in Western countries is provided to guide vascular specialists in the evaluation and implementation of AI applications in their practice.

SOCIAL AND ETHICAL CONCERNS RAISED BY ARTIFICIAL INTELLIGENCE

Machine learning (ML) and deep learning (DL) are subsets of AI that enable mapping data patterns without *a priori* hypothesis. Large representative health data are usually necessary to train and test the algorithms. Access to and use of medical data raise major concerns regarding confidentiality, security, and data protection against cyber attacks.⁴ In addition, data management, governance, ownership, and sharing can be very challenging to solve, especially in the context of international multicentre collaborations.⁵ AI and ML models are potentially subject to algorithmic bias due to hidden bias that can be embedded in the input data and due to bias that can be generated by the algorithm itself.⁴ It raises concerns about accuracy and potential discrimination of subgroups of patients. The implementation of AI applications should guarantee equity and access to high quality care for all patients. Large multicentre studies are necessary, and in the field of vascular surgery, international registry collaborations such as VASCUNET or the Society for Vascular Surgery Vascular Quality Initiative might help to train and validate AI models.⁵

Interpretability and explainability is also very challenging as it is difficult to understand how the output decision is reached by the models.^{4,6,7} The question of transparency is at stake and intellectual property rights bring additional

challenges to communicate detailed computational and technical information.⁷ In any case, users should be cautious, keeping in mind confidence limits and the potential uncertainty of the models.^{4,6} Finally, for health professionals, potential risks related to AI have to be anticipated. The first one relates to automation bias that can be unintentionally induced by AI due to over reliance on technology.⁶ The second concerns the risk of progressive deskilling induced by a decrease of human know how and reduction of training opportunities.⁶ This is especially the case in vascular surgery where particular attention should be paid as the technical procedures can be complex and rapidly evolving. The impact of AI on human relationships is a key aspect raised by patients, the public, and society. The physician patient relationship is based on trust, knowledge, regard, loyalty, and empathy.⁶ Implementation of AI models in clinical practice should aim to enhance care without replacing the expertise of health professionals, responsibility, and support all through the care of patients. Patients should be informed and give their consent when an AI system is used. The main questions that patients and health professionals may ask in the context of vascular surgery include: What are safety guarantees, clinical benefits, and potential risks? What happens if an AI or ML system or an AI driven robotic procedure leads to a wrong clinical decision or adverse events? Whose responsibility is it and what procedure should apply?

ETHICS PRINCIPLES AND COMMITMENTS RELATING TO ARTIFICIAL INTELLIGENCE

Ethics in AI aims to cover these concerns, and the main general principles and commitments have been described. The United Nations Educational, Scientific and Cultural Organisation listed 10 core principles lay for a human rights centred approach to the Ethics of AI,⁸ and the EU's AI high level expert group described seven key requirements that AI systems should meet.⁹ It includes human agency and oversight, technical robustness and safety, privacy and data governance, transparency, diversity, non-discrimination and fairness, societal and environmental wellbeing, and accountability. The Organisation for Economic Co-operation and Development Council on Artificial Intelligence also defined recommendations and guidelines.¹⁰ Various ethics, canvas, and principle oriented checklists have also been elaborated by various institutions such as the Open Data Institute, the 12 step guide by the World Economic Forum,

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the blueprint for an AI Bill of Rights elaborated by the US White House Office of Science and Technology Policy, the AI risk management framework released by the National Institute of Standards and Technology.^{11–14} Even technology companies such as Apple, Google, IBM, and Microsoft have a partnership on AI to establish a common ground between entities to unite force for good in the AI ecosystem.¹⁵ Finally, commitments for ethics and trustworthy AI require a co-creation process and involvement of patients as well as medical societies and associations that have also contributed to define main principles.

LEGAL FRAMEWORK

While ethical commitments serve as guidelines, AI and ML models have to comply with current regulation and legislation. For Europe, when the models use health data, they have to respect the General Data Protection Regulation.¹⁶ Software, like medical device and machine learning medical models are also subject to CE mark quality assurance that attests conformity to the general safety and performance requirements in order to access the European market. The EU's AI Act aims to build a global standard in Europe.¹⁷ The first draft was published in April 2021 by the European Commission, and it is expected that the AI Act will come into force after being published in the Official Journal of the European Union in late 2023 to early 2024.¹⁷ In the United States, the Health Insurance Portability and Accountability Act defined requirements and the legal framework for the use of medical data.¹⁸ The Food and Drug Administration has also started to elaborate guidance on AI and ML software as medical devices.¹⁹ In 2022, the Algorithmic Accountability Act (AAA) was introduced in the US Senate and the House of Representatives.²⁰ It aims to address public concerns about the use of AI driven automated decision making systems and proposed organisational deployment to identify and manage related social, ethical, and legal risks. However, it remains unknown whether the AAA will pass and become law. Defining responsibility and accountability is a very challenging process as its perception might differ depending on nations, cultures, and social context. It involves various actors such as designers, developers, individual or corporate owners, societal actors, regulators, legislators, users, and consumers, and requires building strong ecosystems to ensure development of responsible AI applications.²¹

CONCLUSION

The complexity of intelligent systems from conception, development and implementation into clinical practice has given rise to the concept of AI ecosystems that are required to manage risks and responsibilities.²¹ Such ecosystems would enable development of a total product lifecycle approach with involvement of multiple stakeholders, proactive risk management, continuous learning and fast adaptation to regulation.⁴ The future impact of AI in

medical practice and management of vascular diseases remain to be defined and shaped. Vascular specialists have a responsibility towards conception, evaluation, validation, definitions of use and implementation of AI models in practice, while keeping their technical and medical skills, maintaining human interaction, empathy, and emotional support.

CONFLICT OF INTEREST

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