



Artificial Intelligence in Trauma and Orthopaedic surgery - EFORT – Ethical guidelines

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Preamble

Artificial Intelligence (AI) is likely to play an ever increasing role in orthopaedic diagnostics, therapy, monitoring and prevention. Sensible and responsible deployment of this technology must be a feature in both research and clinical settings. Demonstrable benefit for both science and the patient must be a guiding principle.

The duty of care to patients must not be overshadowed by our desire for progress. Autonomous Surgical systems should not be deployed if they fail to align, at any stage, with medical ethics, dignity, human rights, freedom, and cultural diversity. Patients should be fully informed, involved and accept to give their consent.

A culture of co-operation, trust and transparency between AI scientists and surgeons must be implemented, guided by European Union law concerning human rights and ethical values.

The principles of biomedical ethics and the 'Key considerations in ethical orthopaedic practice', as formulated in the statement from the EFORT ethics committee entitled "**ETHICAL ORTHOPAEDICS FOR EFORT (2014)**" must guide AI research, development and use at all stages in the lifecycle of AI applications.

1. Respect for Autonomy

Informed consent by patients is a prerequisite for any research on, or use of, AI in the clinical care pathway to replace or reinforce any step in that pathway that the patient could reasonably have expected a clinician to perform.

The privacy of our patients must be respected and protected. It is the responsibility of professionals to maintain the privacy and integrity of data describing individuals. This includes taking precautions to ensure the accuracy of data, as well as protecting them from unauthorized access or accidental disclosure to inappropriate parties.

While surgeons and designated researchers must enjoy the right to access, manage and control the data they generate, these must be made accessible and understandable to patients, too. Patients have the right to have their data deleted and to opt out of the procedure at any time.



All persons involved in patient care must:

- a) not mislead patients about the collection, use, or communication of their healthcare information;
- b) enable and facilitate patients' ability to access their data and, in accord with independent ethical and legal standards, to correct their data if it is not correct;
- c) ensure confidentiality: the principles of honesty and transparency extend to issues of confidentiality of information. Whenever an explicit promise (either in written or verbal) to honour confidentiality has been made, it must not be broken without explicit consent of the patient, or following legal requirements or other principles of this Code.

Incentives for surgeons, which may cause conflicts of interest, must be avoided.

2. Non-Maleficence

Teams developing AI surgical systems should actively cooperate with local, national and, where possible, international scientific societies to ensure that every locality-specific safety issue is considered and all ethical concerns are addressed.

New AI systems must be made available only to those properly instructed in their use, and only after their safety and efficacy has been proven.

No system should be introduced without rigorous Hospital Ethical Committee approval and appropriate clinical trials.

It is the responsibility of the clinician, rather than the AI designers and technicians, to take control of any clinical or research implementation of AI. Should problems arise with new AI systems, their implementation must be suspended until investigations have reported.

AI in use should be continually maintained, re-evaluated and improved.

3. Beneficence

Surgeons and other parties involved in the development and implementation of AI should make sure that any application used in patient care serves a medically sensible purpose and is aimed at positively influencing the wellbeing of the patients.

Applications proving to be ineffective or medically useless should be abolished.

The targeted standard of care should be explicitly mentioned, and must be transparently defined according to the present state of the art.

Quality improvement and ongoing monitoring of the benefit to patients should be the goal of all surgeons involved in the development and use of AI.

Personal contact with patients must not be eclipsed by AI, without solid evidence that this change benefits the patients.



4. Justice

Active participation of all parties involved in the clinical and research use of AI must be guaranteed. Assessment and allocation of investment to surgical AI research funding should involve surgeons and patient representatives from the start, and be accompanied by vigilant re-evaluation to ensure its continued safety and patient benefit. Constructive and healthy interchange between surgeons, AI researchers and policy makers must be fostered. AI applications of proven efficacy must be assessed against alternative applications so that cost effective technologies can be made accessible to all patients in need. Target groups must be identified and prioritised fairly and transparently.

AI applications must be designed, used and maintained with the constant goal of reaching out to all segments of a population potentially benefited by them.

Algorithms integrated in AI should not permit considerations “of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between [...] duty and [...] patient” as stated in the Declaration of Geneva of the World Medical Association.

If we follow these principles, we will see the safe and productive use of AI technology develop to the benefit of our patients.