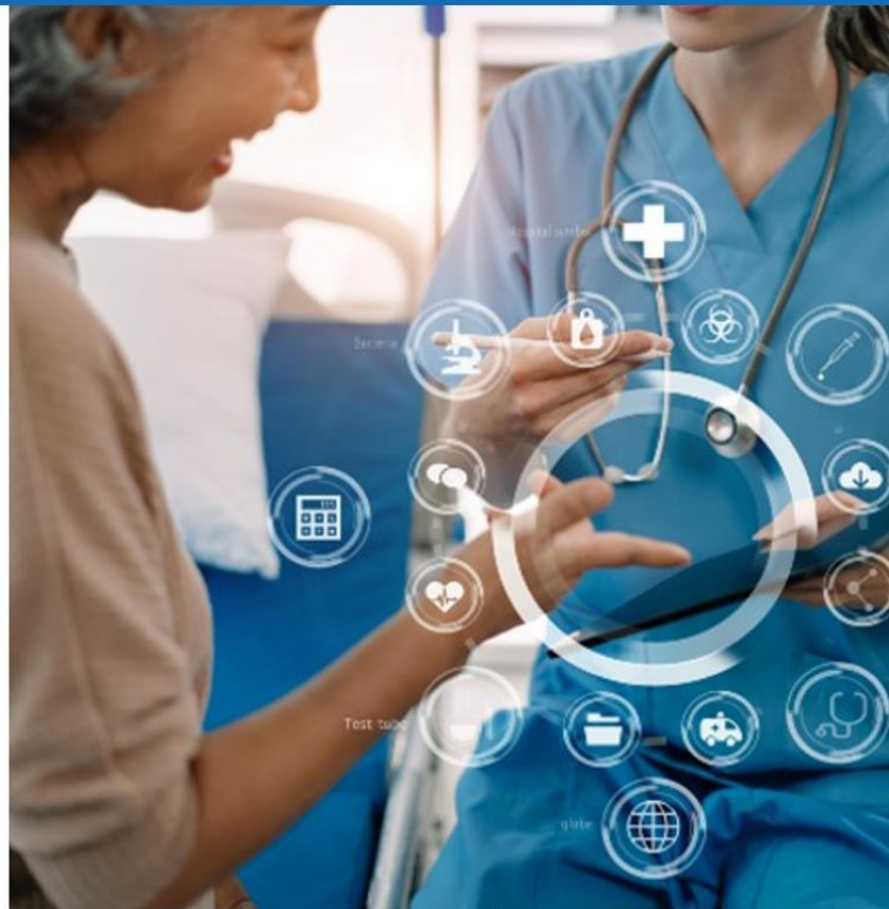


# THE APPLICATION OF ARTIFICIAL INTELLIGENCE IN HEALTHCARE AND ITS IMPACT ON THE 'PATIENT-DOCTOR' RELATIONSHIP

## ESSENTIAL ELEMENTS



Steering Committee for Human Rights  
in the fields of Biomedicine and Health(CDBIO)

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The Council of Europe aims to protect human dignity and the fundamental rights and freedoms of the individual regarding the application of biology and medicine. Major technological breakthroughs in artificial intelligence, have the potential to advance biomedicine and benefit healthcare, yet uncertainty exists about their impact and direction of developments.

The report addresses AI in healthcare, including applications that are used by health care professionals as well as applications that are used by the patients themselves (apps prescribed by a doctor, but also independently used apps such as symptom checkers or health data trackers). With its focus on the patient-doctor relationship the report does not focus on AI development nor on AI-related research that includes human subjects.

The report focuses on selected human rights principles, as referred to in the Oviedo Convention, of particular relevance to the therapeutic relationship, namely autonomy, professional standards, self-determination regarding health data, and equitable access to health care.

AI systems have the potential to bring about a significant transformation of the patient-doctor relationship, although the effects of its deployment on the relationship have yet to be seen. That said, doctors' expertise might become challenged but also significantly increased by high-performing decision support in various domains of healthcare. Patients who decide to use AI systems by themselves, might rely less on the advice of health professionals. Challenges lie in misplaced trust, overestimation of technological performance and testimonial (in)justice as to the question of whom to trust in the patient-doctor encounter.

A sustainable approach to providing access to health care using AI systems should be one which includes a human rights perspective in order to safeguard well-being and protect the dignity of everyone. This human rights perspective should be 'end-to-end' throughout a patient's healthcare journey.

There must be trust in the professional standards which scrutinise the safety, quality and efficacy of AI systems; should this falter (e.g. when AI systems are considered to be inscrutable, inconclusive and even misguided) patient autonomy will be weakened.

A major challenge lies in ensuring that AI systems (their data and models) are empirically sound and robust, accurate, and their results consistent and reproducible (e.g., based on independent standards or expertise, such as independently testing algorithms). Standards for clinical trials involving AI systems are necessary to ensure the safety, quality and reliability of trial results. This will allow AI systems to be more easily appraised by investigators and others, such as regulators.

The trustworthiness of AI systems in healthcare depends on human oversight and the 'explainability' of AI outputs. The "black box" character of some AI methods has been criticised as having a bearing on the risk of bias and discrimination without good options for detecting such failures in performance. The responsible use of AI in healthcare relies at least on a basic understanding of the strengths of AI recommendations.

In their design, development and training phases, action is necessary to address biases in AI systems to mitigate the potential for discriminatory access to healthcare affecting people and groups (based on e.g., race, gender, age or disability). There is an opportunity for AI systems to mitigate pre-existing bias found in modern medicine. In the future, AI might provide options to redress differences to whom fairness is owed (e.g. older people, lower socio-economic groups, ethnic minorities etc).

Patients may find it difficult to understand what AI systems are, why are they being relied upon, and how they are being used. While some might argue that doctors have discretion to decide whether to inform their patients about their reliance on AI systems, this should not preclude them from seeking out information and explanations to consent to health interventions.

Patient autonomy necessitates more information, explanation and transparency than less. This includes patients knowing when they are interacting with an AI system, and knowing how to consent especially in cases when the deployment of AI systems leads to health care administered with less and/or without recourse to the therapeutic hand of the doctor. When the risks to the patient are high, there should be the possibility to distance human consent from AI system outputs.

Where required, patients' consent to the use of their data by AI systems should be free, express and informed. They should know about what is collected and how it may be shared. They should be provided with assurances and possibly different types of consent options.

Healthcare providers should ensure that safeguards are in place to protect the privacy and confidentiality of patients throughout their healthcare journey, especially at the source of its collection. To this end, there should be ever more vigilance with patient data, mitigating any inadvertent or otherwise ambiguous data sharing with third parties.

AI enabled care should never be a substitute for people (in vulnerable situations) who need human professional contact and guidance. Careful attention should be paid to not putting the patient in a worse position if AI systems are not used or otherwise denied.

Doctors and other healthcare professionals will require support in adapting to AI systems which guides their actions. They will need to be informed, explained and trained accordingly, with considerable emphasis on their critical role in protecting and safeguarding patient well-being and quality of care.

Above all, AI systems should never undermine the therapeutic relationship however good the intentions are. They must be made transparent to patients and doctors so that they are aware of what is running in the background. Patient autonomy and agency, coupled with the human oversight of health professionals, are the path forward to strengthening the therapeutic relationship impacted by AI systems.