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POLICY BRIEF

Reviewing the Ethics of AI in health and healthcare

January 2024

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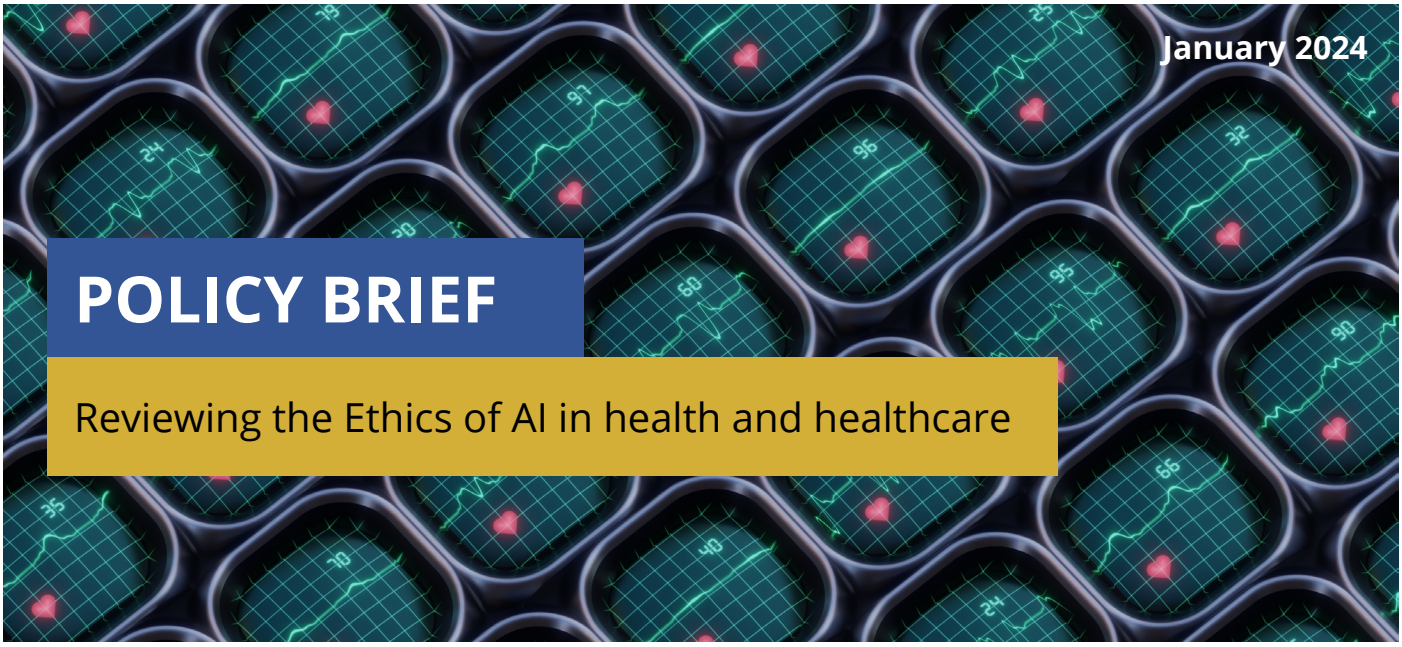

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Why this policy brief on Ethics of AI in health and healthcare?

Artificial Intelligence (AI) in healthcare refers primarily to the application of machine learning to improve various aspects of healthcare and medical practices, e.g. diagnostics or remote consultation. AI has the potential to enhance accuracy, speed, and efficiency of medical treatment by automating standard or repetitive tasks, as well as to help maintain a better organized and efficient doctor-patient relationship. Research Ethics Committees (RECs), traditionally focusing on protecting participants' well-being, face a number of challenges when reviewing research involving AI. This policy brief highlights three key issues and provides recommendations for risk mitigation, specifically targeting ethics experts and REC members.

Current challenges

1. Ethics experts' difficulties in understanding the technical aspects of AI

AI systems are becoming increasingly well-known and available in healthcare, but their operation is technically complex and often non-transparent to medical professionals who are not trained in computer science. To effectively regulate AI in healthcare, experts must knowingly address key technical complexities, e.g. finding the right equilibrium in the 'efficacy vs transparency' dilemma requires understanding of explainable AI. Understanding the limits and meaning of privacy and security is also paramount, as AI algorithms often use sensitive patient data. Additionally, achieving seamless interoperability and integration of AI solutions with existing healthcare practices (e.g. data formats) is challenging. Furthermore, tackling algorithmic bias (e.g. gender variations of diseases) is crucial to produce correct outcomes and to foster trust of healthcare professionals in AI systems.

2. Discrepancies in the existing ethical review of AI biomedical research

Biomedical research involving AI often escapes traditional ethical review by RECs due to differences in the definitions of medical research or research participant qualifications in different

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countries. Additionally, non-biomedical fields of research in Europe often lack settled ethical review procedures. As a consequence, AI systems are either unreviewed or assessed using standards different from those applied to medical devices. CE certification is not yet widely used. The narrow mandate of RECs attached to public institutions can also pose challenges, as AI systems are primarily developed by commercial companies without any REC available to assess their research.

3. Future uncertainty

When medical RECs assess AI research in healthcare, they primarily focus on consent and privacy matters in building training datasets. Their involvement often ends here, despite the possibility of significant ethical challenges during the use of AI systems after the end of the research project. Anticipating future explainability gaps or emerging ethical issues is challenging due to uncertainty and lack of transparency in machine learning. Possible effects of AI systems on healthcare professionals (e.g. overconfidence or excess of trust in AI systems) are rarely considered. In terms of data governance, uncertainty about future applications also requires broad consent or consent waivers. Lifecycle risk management may require new methodologies of ethical assessment not limited to compliance with existing regulation.

Recommendations

1. Adapt the composition of RECs to include AI experts

Like in other fields using new AI solutions, envisioning potential ethical issues of AI applications in healthcare requires appropriate scientific and technical expertise. To tackle this challenge, research institutions should consider integrating 'AI subcommittees' (REC assemblies specialized in AI projects) into existing RECs mandated primarily for health-related research, or alternatively establishing dedicated 'digital ethics committees' (DECs). Without replacing existing RECs, these bodies would bring together AI experts, research professionals, and specialists in social and human sciences. They would conduct ethics reviews for AI-related research projects and may occasionally serve as advisory bodies for policymakers. By allowing sufficient mutual learning time and providing appropriate training and resources, the ethics appraisal process can be significantly widened and improved to cover all AI-related research projects in healthcare.

What is AI in health and health care?

Technology that can automate everything from predictions, recommendations and decision-making has enormous potential for use in healthcare. AI is already used in some high-income settings, but there remains a flood of legal, ethical and regulatory questions to be answered.

2. Set uniform and coherent 'AI in healthcare' guidelines across EU member states

To address discrepancies in the ethical review of AI-related research in healthcare and to avoid ethics dumping, collaborative efforts among EU member states are essential. Homogenized guidance on ethical appraisal of AI-related research in healthcare should be provided at the EU level to ensure consistency in RECs' evaluations and to facilitate cross-border research projects, empowering researchers to navigate regulatory challenges effectively. Addressing regulatory disparities between countries (e.g. the French CCNE

Relevant regulatory aspects

As long as the EU Regulation on Medical Devices (EU 2017/745) and the EU Regulation on In Vitro Diagnostic Devices (EU 2017/746) apply, AI systems falling under these Regulations are considered to be high-risk AI systems in the sense of the Proposal for a regulation of the European Parliament and of the Council on harmonised rules on Artificial Intelligence (Artificial Intelligence Act). This position is consensual between the EU Commission, Council, and Parliament. The classification of AI systems in healthcare as "high-risk" will entail mandatory certification measures.

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recently adopted an opinion on the use of AI in medical diagnostics, while most other EU members do not provide any guidance at all), as well as between the public and private sectors, is crucial. To achieve this, comprehensive and mandatory training for ethics reviewers on the application of EU HLEG guidelines for Trustworthy AI and the HLEG ALTAI checklist is recommended.

3. Develop REC methodologies beyond compliance

The use of AI systems in healthcare requires ongoing evaluation beyond a one-time compliance check. RECs should be involved in the ethical appraisal of AI systems at regular intervals during the design process, following the 'ethics-by-design' methodology via regular consultations involving all stakeholders (designers, medical professionals, and patient organizations or patients). The frequency of this monitoring should be determined based on foreseeable risk to ensure that the ethics recommendations issued by RECs are proportionate and relevant. RECs should move away from assessing compliance toward helping researchers to perform ongoing ethical reflection, anticipation, and evaluation.

Further Reading

The AI Act website
Monitors developments around the EU AI Act
https://artificialintelligenceact.eu

Ethics guidelines for trustworthy AI
By the High-Level Expert Group on AI, an independent expert group set up by the European Commission (EC)
https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai

The CCNE (France) opinion on the use of AI in medical diagnostics (English version)
Joint opinion by the National Advisory Ethics Council for Health and Life Sciences (CCNE) and the National Digital Ethics Steering Council (CNPEN)
https://www.ccne-ethique.fr/sites/default/files/2023-05/Opinion%20No.141.pdf

Ethics By Design and Ethics of Use Approaches for Artificial Intelligence
Provides guidance for an ethically-focused design of AI systems
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf

EU ethics appraisal scheme
Has a dedicated chapter (chapter 8) on the EC guidelines for AI research
https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

How we did it

This policy brief is based on research conducted in *Task 2.2: Development of recommendations for addressing ethical challenges from research in new technologies*. Using desk research, expert consultation and a leadership roundtable, irecs identified ethical issues in AI in health and healthcare as well as challenges faced by REC members and ethics appraisal experts. Recommendations were drafted with iterative input from irecs partners. The Stakeholder Advisory Board gave feedback and a dedicated focus group was organized by EUA to discuss and refine the recommendations.

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About irecs

"Improving Research Ethics Expertise and Competencies to Ensure Reliability and Trust in Science"

irecs aims to advance research ethics expertise and competences in new and emerging technologies. The project will focus on 4 emerging technologies (AI in health and healthcare; Extended reality; Genome editing (human/non-human); Biobanking) and will develop, implement and disseminate training material for research ethics reviewers and (early career) researchers.

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Consortium: 17 organizations from 11 countries

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