The regulation of AI in medicine: an analysis from a multileve and comparative perspecitve

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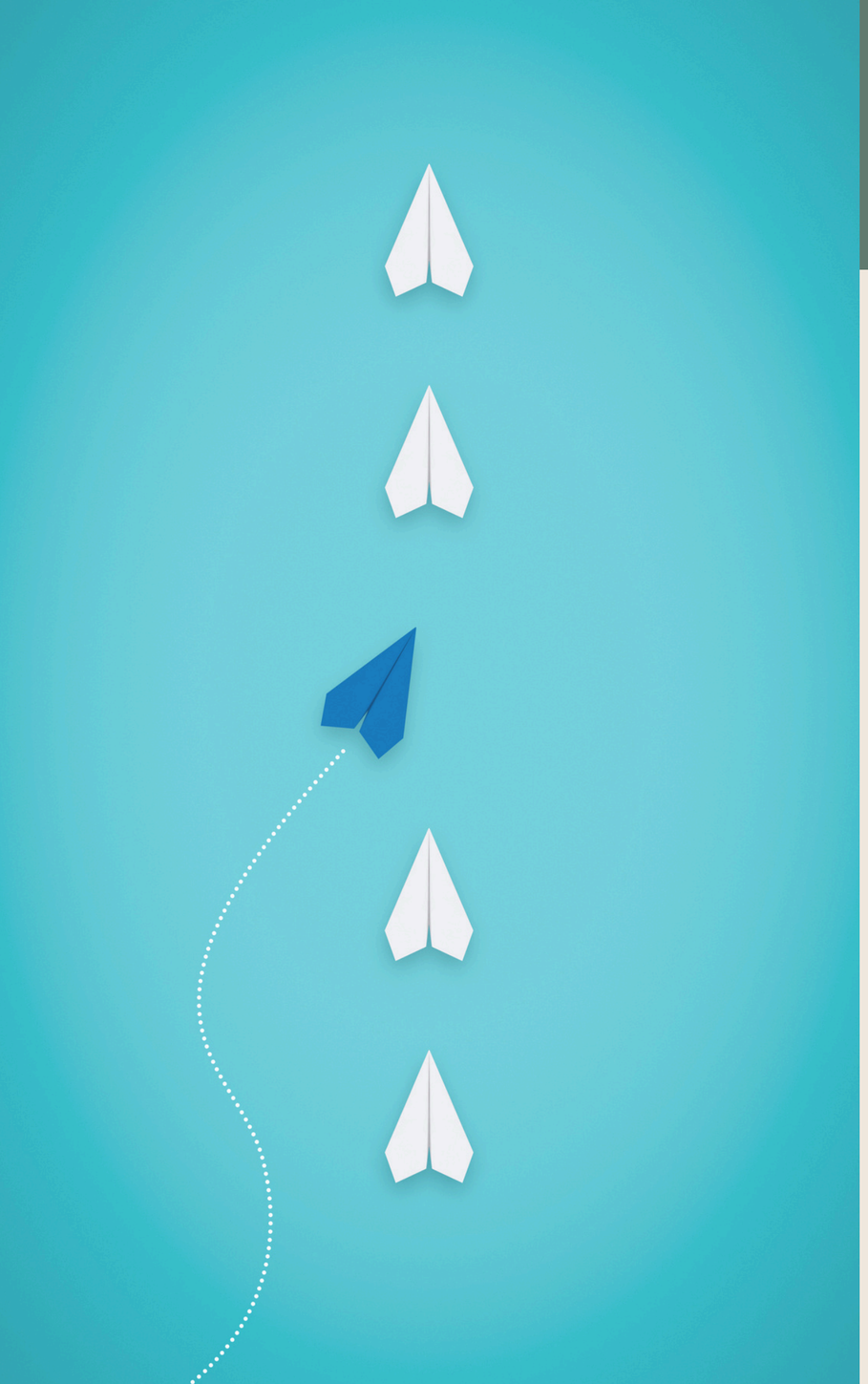
The rise of AI in medicine and the related emerging issues

- Personalization
- Accuracy
- Data and dataset
- Prevention & well-being
- Opacity
- Patients' awareness
- Biases
- Deskilling



The rise of AI in medicine and the related emerging issues

AI affecting the legal dimension and framework of doctor-patient relationship

AI affecting the funding legal values of the doctor-patient relationship

1. Doctor professional autonomy and clinical expertise
2. Patients' decision-making autonomy (informed consent)

AI and doctor-patient relationship

How to avoid a possible negative impact of AI within doctor-patient relationship still preserving the protection of people fundamental rights

The regulation of AI in the doctor-patient relationship in a comparative perspective

Looking at the current regulations dealing (also) with the use of AI in the mentioned field

Understanding which tools, mechanism and safeguards could be aimed at protecting people's fundamental rights

1. Right-based approach (France and Italy)
2. Procedural-based approach (US and UK)
3. "Hybrid" approach (EU)

The right-based approach: France

ART.17, LOI DE BIOÉTHIQUE (ART. L. 4001-3 CODE DE LA SANTÉ PUBLIQUE)

- **Healthcare professionals duty to inform patients about the use of AI for diagnosis, treatment and prevention purposes and provide interpretation of the final outcomes**
- **Healthcare professionals must be informed about the use of AI and access data used and final results**
- **AI system developers must ensure explainability, so that users can understand and know how the system works**

The right-based approach: Italy

DISEGNO DI LEGGE DISPOSIZIONI E DELEGA AL GOVERNO IN MATERIA DI INTELLIGENZA ARTIFICIALE (ART.7)

- **Prohibition on the use of AI to determine access to healthcare services based on discriminatory criteria**
- **Right of patients to be informed about the use of AI, the diagnostic and therapeutic benefits of AI, and the decision-making logic used by the system**
- **Medical decisions (diagnosis, prognosis, and treatment) must remain a healthcare professionals human prerogative**
- **The dataset must be reliable (monitoring to minimise the risk of errors)**

The right-based approach: distinguishing features

- Both regulations regarding the specific application in the healthcare (and doctor-patient relationship) field
- Main recipients of regulations: healthcare professionals and patients
- Hard law
- Provision of specific obligations, duties and rights (explanation, access dataset, informed consent)

Attempt to provide specific guarantees protecting both patients and doctors positions and interests

The procedural-based approach: USA

THE FDA GUIDELINES

- **Good Machine Learning Practice for Medical Device Development: Guiding Principles (2021)**
- **Final Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions (2024)**
- **Draft Guidance: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations (2025)**
- **Transparency for Machine Learning-Enabled Medical Devices: Guiding Principles (2021)**
  - **Ensure AI transparency for all those involved in patient care and for patient themselves;**
  - **Ensure patient information, risk management, health equity and patient-centred care**
  - **Know how AI works, limitations, risks and decision logic of the system**
  - **Ensure responsible and personalised information**

The procedural-based approach: UK

MEDICINE AND HEALTHCARE PRODUCTS REGULATORY AGENCY (MHRA)
IMPACT OF AI ON THE REGULATION OF MEDICAL PRODUCTS (2024)

Implementation of the pro-innovation approach White paper in the healthcare field

- **Transparency and explainability of AI:** information concerning how AI works and design taking into account the intended users (healthcare professionals)
- **Fairness:** ensuring equitable access to safe, effective, and high-quality medical devices for all individuals who use them (fighting gender, ethnic and socio-economic biases)
- **Accountability and governance:** full traceability and accountability of manufacturers for how AI models meet intended use as well as the impact of changes
- **Contestability and redress:** enabling patients anyone to report concerns to the MHRA about a medicine or device, including one incorporating AI

The procedural-based approach: distinguishing features

- Both regulations regarding the specific application in the healthcare field
- Main recipients of regulations: providers and developers of AI-based medical devices
- Soft law (guidelines and white paper) developed by regulatory agencies
- Provisions that mainly concern the development and production of AI-based MD

General lack of specific guarantees protecting both patients and doctors positions and interests

The hybrid approach: EU

EU REGULATION ON ARTIFICIAL INTELLIGENCE (AI ACT)

- Medical devices

High-risk systems

- **Risk management system;**
- **Data governance;**
- **Technical documentation;**
- **Log record;**
- **Transparency;**
- **Human oversight;**
- **Acuracy, robustness and cybersecurity**

- Provider obligations;
- **Deployer obligations (professional user, the doctor)**
- **Human oversight duties**

The hybrid approach: distinguishing features

- General regulation on AI development and use
- Main recipients of regulations: providers and professional users of AI
- Hard law
- Provisions that concern both the production (requirements) and the use (deployers obligations, human oversights guarantees) of AI

Opportunity to create a multilevel approach and a multilevel protection of doctor and patients using AI

The multivel approach and protection of people fundamentla rights in EU

AI Act

France

Italy

MS

Complementing the AI act legal framework with specific regulation of MS (principle of conferral and principle of subsidiarity)