Medical liability and artificial intelligence in the EU countries

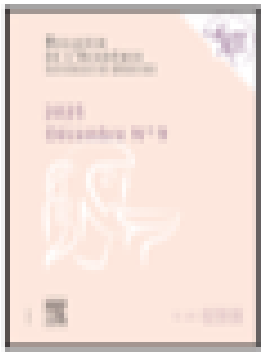
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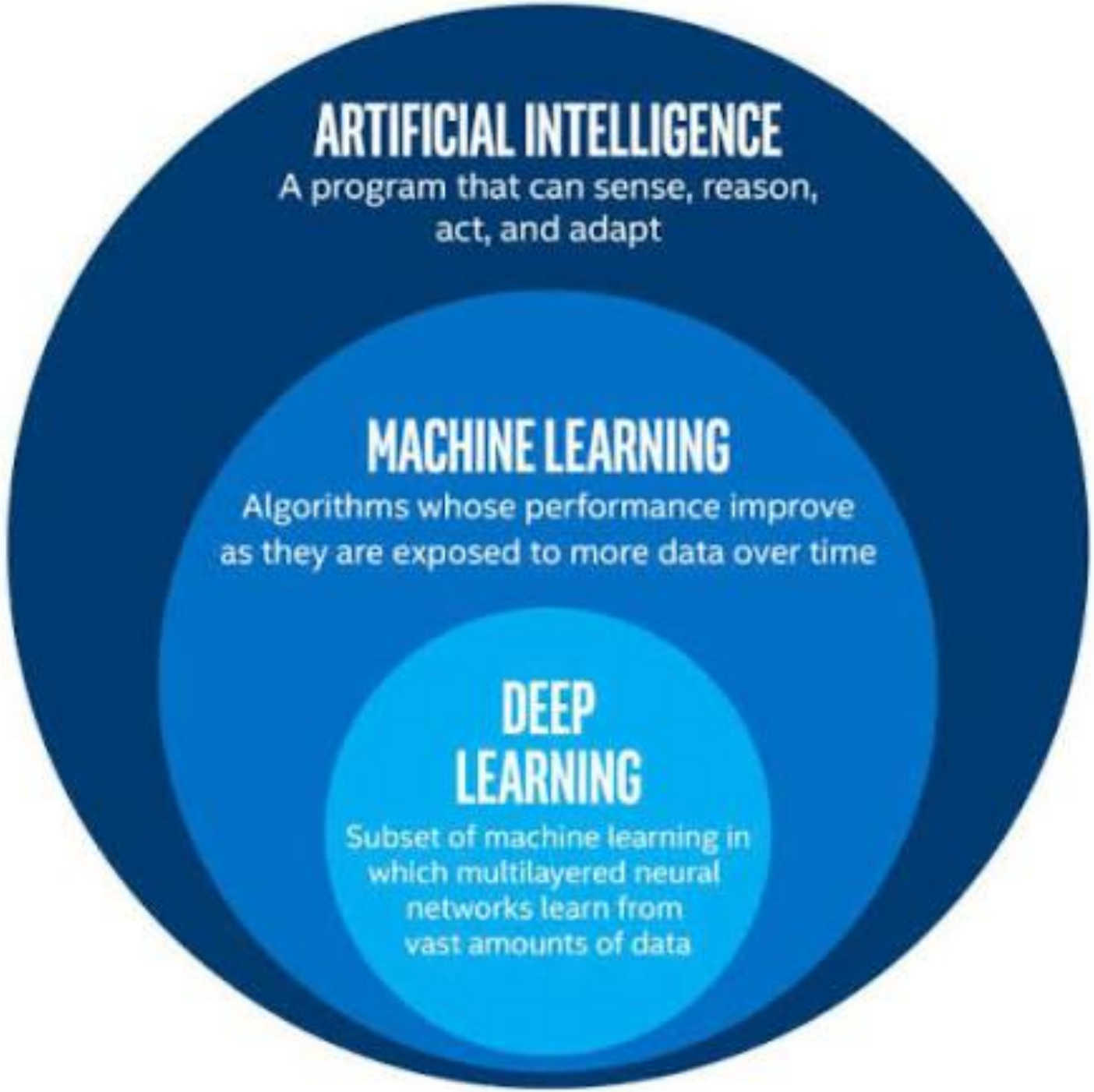
Artificial Intelligence and medical liability. What are the issues?

Dominique Lecomte*, Christian-François Roques-Latrille, au nom d'un groupe de travail de la commission 5 de l'Académie nationale de médecine[1]

Académie nationale de médecine, France

Some definitions

- **“AI systems”** are numeric systems designed to imitate or reproduce certain human intellectual capacities: learning, reasoning, perception, problem-solving, decision-making, ...
- They use systems of "**algorithms**" which are "sequences of detailed and ordered information whose data allows problems to be solved, certain tasks to be performed directly".
- Their conclusions are **only valid for the data** on which they are based.


ARTIFICIAL INTELLIGENCE
A program that can sense, reason, act, and adapt
MACHINE LEARNING
Algorithms whose performance improve as they are exposed to more data over time
DEEP LEARNING
Subset of machine learning in which multilayered neural networks learn from vast amounts of data

AI and medical exercise

1. **MEDICAL**
   1. **DIAGNOSIS** (early detection, diagnostic optimization, telemedicine, severity scores, fault detection on medical devices, strengthening of prevention strategies, screening, …),
   2. **MEDICAL AND SURGICAL THERAPEUTICS** (**prescriptions** with a high risk of error, serious **adverse events**, **personalization** of treatments by evaluating specific patient data, use of particular tools such as **surgical robots**, companion robots, **pharmacovigilance** with notification of possible adverse events, …),
   3. **MONITORING** of **chronic** and/or **complex patients**,
   4. **PREVENTION**, prediction through **patients « profiling »**,
   5. **TRAINING** (Literature review, confrontation **AI-EBM**, …).
   6. **SCIENTIFIC INVESTIGATION**, …
2. **OFFICE AUTOMATION**
   1. **administrative activities** (patient **files**, medical **reports**, medico-administrative **databases**, digital **prescriptions**, etc.).
   2. **work organization** (**appointments**, **scheduling**, **documents** creation, …).

Legal framework in EU member States

1-European regulations transposed into laws of member states

- **General Data Protection Regulation (GDPR)(2018)**
- **Artificial Intelligence Act (AI Act) (2024)** *Art 14 :* **Human supervision, "human guarantee"** *(de facto legal obligation), requires* ***understanding the capabilities and limitations of AI*** *systems in healthcare and retaining the decision-making role.*
- European **directive** on **liability for defective products (2024):**
  - **Sharing of responsibilities** between **suppliers and deployers.**
  - Liability for **fault,** with **presumption of causal link.**

2-National laws on medical liability: ex. France

- **Relevant Jurisdictions**
  - **Judicial** (civil, criminal), **Administrative, Disciplinary** (Medical Board)

- **Texts:** Public Health code, « numeric information and freedom » law (1978), deontology (medical ethic) code, …

EU AI Act: 3 categories of actors - 4 levels of risks

ACTORS

- **Suppliers**
  - Designers
  - Manufacturers,
  - Developers, …
- **Deployers**
  - **health professional**,
  - spa contractors, …
- **Concerned Persons**
  - **Patients** , curists, …

RISKS

- **Unacceptable**: dangerous for civic rights
- **High**: **medical devices**
- **Medium**: video-games
- **Low**: chat bot

Cases of medical liability

- **Information and consent** +++
- **Healthcare quality**

Care conform to the present state of the art and with proportionate risk

  - ***Diagnosis***
  - ***Therapeutic*** *choices,*
  - ***Care*** *and* ***monitoring***
- **Defective product use**
  - ***Doctor,***
  - ***Care facility,***
  - ***Supplier, ...***
- **Data**
  - ***Access,***
  - ***Confidentiality,***
  - ***Protection, ...***

In France, at the end of 2025 no legal case in progress.

Principles of liability – the steps

- **Demonstration** of the **existence of a fault** .
- **Existence** of a **harm** (damage and/or **loss of opportunity**).
- **Demonstration** of the **relation between the fault and the harm.**
- **Quantification** of the **harm** (damage, loss of opportunity, …).
- **Identification of** the **modalities** of fault sanction and damage reparation.

*In **France**: **doctors' liability** is engaged only in case of **fault** and damaging **medical events without fault can be repared** thanks to national solidarity.*

The main key points on AI use in medicine

- **Patient information** (clear, understandable, and **traceable**) if AI is used.
- "**Mastery" of the approved AI tool** and **validation of results** (human oversight).
- **Training of healthcare professionals** (University, Continuing Medical Education, professional and scientific organizations, interaction between suppliers and deployers, etc.).
- **Protection of health data** (hosting on HDS-certified sites).
- **Strong traceability** (liability at the time of the events, in case of harm).
- **The supplier**: Quality of algorithms, certification of tools **(CE marking),** Integration of **monitoring and evaluation mechanisms** into the tools.
- **Patients (expert patient +++)**: AI training.

Should physicians use available AI?

- **Risks:** AI **unused**, **ignore** or **overconfident** (on AI results) **.**
- **Not using AI (when existing) is unethical** (Académie Nationale de Médecine, 2024).
- The **patients** must be **informed of AI use and proposals.**
- **The doctor** must consider **AI proposals** and be able to **discuss them to reject or accept** (Human guarantee. AI Act Art. 14).
- It is **not compulsory to accept the AI proposals.**
- **AI** proposals **acception or rejection** must be based on the **scientific evidence** at the time of the AI use.
- The doctors must be able to **produce the scientific basis** (at the time of the use) of their decision, **later** (liability at stake) **. Importance of traceability.**

Use of AI by operators of thermal facilities

- **Software used for treatment planning, monitoring the distribution of thermal products**, etc., is considered a "product," and any **harmful** malfunction will be classified as a **defective product**.
- In the event of a **substantial modification** to a device and/or software by the operator of a thermal spa, the operator would assume the original manufacturer's legal responsibility for the risks associated with this modification.
- **Cybersecurity** vulnerabilities in the infrastructure also constitute a criterion for a defect.

Some final recommendations

- **AI must remain an aid, not a replacement,** for healthcare professionals, requiring **constant vigilance** (algorithmic biases – hallucinations –, overconfidence, rapid developments, etc.).
- **Conscientious care based on scientific evidence.** If AI is recommended by agencies, learned societies, etc., any patient deprived of it can consider themselves to have missed an opportunity.
- **Physicians must possess the necessary knowledge about AI.**
- **Traceability (information, consent, decision) and data protection** are essential **(faults easy to demonstrate in these fields).**


Thank you for your attention