Medical Diagnostics and AI: Ethical Issues

Joint Opinion of the French National Consultative Ethics Committee on Life Sciences (CCNE) and the National Pilot Committee on Digital Ethics (CNPEN)

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Conférence du 23 mai 2023 / Comité de la prévention et de la précaution

Paris

Introduction

- Medical devices using AI are developping very quickly.

- We call them AIMDS (AI in Medical Devices Systems)

- They might be of great help for medical doctors. But they also contain a certain amount of threats for patients, for the medical system and for the doctors.

- How can medical doctors and the medical system make the best use of these devices while at the same time **keeping the right distance** to the results they propose?

- Prime Minister Edouard Philippe asked CCNE and CNPEN to produce an opinion on the question. What I am presenting here is the answer to the question resulting from a collaborating work of both committees. The Opinbion was sent to the government in Dec. 2022.

Two Committees

- Comité Consultatif National d'Ethique
  - National committe, independant, created by President François Mitterrand in 1983. Dedicated to questions related to life sciences and healthcare.
  - Committee of 46 persons, headed by Jean-François Delfraissy.
- Conseil National Pilote d'Ethique du Numérique
  - Equivalent to the former one but specially dedicated to the digital world.
  - In the process of being officially institutionalized.
- It is all consultative. It is two committees of wisemen without direct legal implication.

Outline

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1 – Examples of medical devices using AI. Advantages and ethical questions

- 1.1. IA in image processing

- Main uses of AI in medical devices: in image processing and recognition: identification of bone fractures, tumor analysis in oncology, or dermatology, images of the retina in opthalmology, for example.
- But produces necessarily errors: False positive and false negative.
- Creates « incidentalomes ». Incidental findings that generate a very heavy – and not necessarily justified – follow up.
- Necessity of a « **human oversight** » as described in the EU AI Act Project, Article 14. "AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use »

1 – Examples of medical devices using AI. Advantages and ethical questions

- 1.2. IA in optimising treatment pathway

- Some devices help orientation of patients to the right specialist, some prioritize emergency cases in the hospital, some help the follow up of patients at home.
- But the problem is that these AIMDS might be primarily oriented towards economical or managerial optimisation, leaving the question of care second.
- AIMDS must be considered as **complementary tools** to respond to the shortcomings of the healthcare system, in particular medical desertification, but should **not be considered as substitute solutions for medical teams.**

1 – Examples of medical devices using AI. Advantages and ethical questions

- 1.3. Wearable devices

- More and more private firms, often disconnected to the official healthcare system sell health wearable devices: measures of heartbeat, arterial tension, sleep quality, etc.

- Raises the question of data protection – where and how are these health data stored?

- Wearable devices could contribute to keeping some patients away from the strictly supervised conventional healthcare system.

- It is important to take into account the **risk of misuse of non-professional advice, unsecured data processing, and illegal practice of medicine**, which accentuates people's vulnerability. AIMDs must follow strict medical practices.

2 – Uncomplete French regulatory framing of AI

- 2.1. For an evaluation of IAMDS that protects the care relationship

- In France, the organization responsible for evaluating AIMDS in terms of their clinical benefits is the « Haute Autorité de Santé ».
- However, it only evaluates medical devices that are reimbursed by health insurance to patients.
- Thus most of the AIMDS are not evaluated in terms of clinical benefit since they are used by health professionals.
- We must create the conditions for trust by encouraging developers to provide a certain **level of explainability** of the AIMDS they put on the market and **limit the promesses** made by developpers.
- More than this, establish a **referential** for benefit evaluation to be used by health professional when buying such devices.

2 – Uncomplete French regulatory framing of AI

- 2.2. Compliance control not yet fully established.

- Compliance control is not benefit evaluation, it makes sure that the AIMDS are not dangerous (benefit risk balance is positive).
- The compliance control is materialized by the "CE" marking and opens up UE markets.
- While EU regulation on the topic moves fast, the term « AI » does not even appear yet in the french Health regulatory system (only « software ») – no specific control
- Control of the vast category in which AIMDS fit requires the intervention of a third-party called « notified » body
- But it is the manufacturer who concieves the demonstration.
- Many things ascape the process, in particular the **biases** generated by the learning and test **databases** are not evaluated

3 - Can AI foster patient participation in the healthcare system?

- 3.1. The new role of digital assistant .

- Understanding AI is not easy for many.

- The danger of the development and accessibility of medical devices integrating AI is that of a deepening of the distance between professionals and technicians in AI and health on the one hand, and patients on the other hand, or between doctors familiar with digital technology and those who remain foreign to it.

- We should promote a **« digital assistant » status**. This person would provide a reason understandable by the patient, or his legal representative, or his trusted person, for the result produced by the AIMDS which is also representative of its operation. It could be compared to the status of "advanced practice nurse" currently being developed in France.

3 - Can AI foster patient participation in the healthcare system?

- 3.2. AIMDS must remain a help to human decision

- The AIMDS must remain an aid to human decision-making. AIMDS results can and should be deliberately ignored by a practitioner if deemed necessary.

- During a course of care, it is necessary to ensure that the patient has been **informed** that the medical team uses a AIDMS, for what reason, and what are the benefits and risks.

- The medical team must beware of ordering interventions without having **verified the reality of the identified risk** and asked for the patient's informed consent.

- It is necessary to adapt the **teaching curriculum** (initial and continuing training) for the medical and paramedical professions so that they train in AI technologies by integrating the consideration of their ethical issues.