## **ALGORITHMS IN HEALTHCARE CONTEXTS**

### **ETHICS AND RESPONSIBLITIES**

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# **DEFINITIONS**

### ALGORITHMS, AI, MACHINE LEARNING, AND DEEP LEARNING



#### Algorithms:

Mathematical methods to automatize a process, largely used in computer sciences to implement software

#### Artificial Intelligence:

Sub-domain of computer sciences dedicated to reproduce « intelligent » skills into softwares<sup>1</sup>

#### Machine Learning:

Sub-domain of artificial intelligence dedicated to create algorithms able to learn from data how to perform a task<sup>2</sup>

#### Deep Learning:

Sub-domain of machine learning dedicated to multi-layer artificial neural networks<sup>3</sup>

- 1. Gao and Ding (2022) The research landscape on the artificial intelligence: a bibliometric analysis of recent 20 years
- 2. Mahesh (2020) Machine Learning Algorithms: a review
- 3. Dong, Wang and Abbas (2021) A Survey on Deep Learning and its Applications

# **DEFINITIONS**

### HEALTH INFORMATION SYSTEMS<sup>1</sup>



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# WHY DEVELOPING HIS?

### TACKLE MEDICAL ERRORS





#### The third cause of death in the US in 2013<sup>2</sup>

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Between 44k and 98k death in the US in 1997<sup>1</sup>

2. Makary and Daniel (2016) – Medical error : the third leading cause of death in the US

# **IMPACTS AND LIMITS OF HIS**

### WORKLOAD AND PATIENT SAFETY: A VICIOUS CIRCLE <sup>1 2 3 4</sup>



- 1. Hall et al. (2016) Healthcare Staff Wellbeing, Burnout, and Patient Safety: A Systematic Review
- 2. Tawfik et al. (2018) Physician Burnout, Well-being, and Work Unit Safety Grades in Relationship to Reported Medical Errors
- 3. West, Dybrye and Shanafelt (2018) Physician burnout: contributors, consequences and solutions
- 4. Dutheil et al. (2019) Suicide among physicians and health-care workers: A systematic review and meta-analysis



# **LEGAL FRAMEWORK**

### **ISO STANDARDS**



#### ISO 13485:

Quality management systems & Requirements for regulatory purposes <u>https://www.iso.org/standard/59752.html</u>



### Applicable to AI ?<sup>123</sup>



### ISO 62304:

Medical device software & Software life cycle processes

https://www.iso.org/standard/38421.html



**ISO 14971:** Application of risk management to medical devices

https://www.iso.org/standard/72704.html

Under development :

- <u>ISO 18988</u>: Application of Al technologies in health informatics
- <u>ISO 24029</u>: Assessment of the robustness of neural networks
- <u>ISO 5259</u>: Data quality for analytics and machine learning (ML)



#### ISO 62366:

Application of usability engineering to medical devices

https://www.iso.org/standard/63179.html



- 1. O'Sullivan et al. (2018) Legal, regulatory, and ethical frameworks for development of standards in artificial intelligence (AI) and autonomous robotic surgery
- 2. <u>Zhao (2019) Improving Social Responsibility of Artificial Intelligence by Using ISO 2600</u>
- 3. Natale (2022) Extensions of ISO/IEC 25000 Quality Models to the Context of Artificial Intelligence

# **AI IN HEALTHCARE**

### A SECOND WAVE OF COMPUTERIZATION



In case of error



# **RISKS AND IMPACTS**

### IN SHORT, MEDIUM AND LONG TERMS

### Reproduction of discriminative behaviors<sup>1</sup>

AI tends to reproduce, or even amplify, discriminative behaviors present in its training dataset

### Loss of physicians' skills and know-how<sup>23</sup>

Physicians do not necessarily detect errors from AI, especially if the AI presents high performances and physicians have strong confidence in the AI

### Negative « rebound effect » on physicians and/or patients <sup>4</sup>

The use of new technologies could conduct in unexpected transformations in healthcare processes

- 1. Zuiderveen Borgesius (2018) Discrimination, artificial intelligence, and algorithmic decision-making
- 2. <u>Tsai, Fridsma and Gatti (2003)</u> Computer decision support as a source of interpretation error: the case of electrocardiograms
- 3. Povyakalo et al. (2013) How to discriminate between Computer-Aided and Computer-Hindered Decisions: A Case study in Mammography
- 4. Bertillot (2016) Comment l'évaluation de la qualité transforme l'hôpital. Les deux visages de la rationalisation par les indicateurs



## **RESPONSIBILITY ISSUES**

### WHO IS TO BLAME?

If a physician uses an AI-based HIS, and this use conduct to medical error, who is responsible?





There is social pressure on physicians who use AI-based HIS<sup>1</sup>

Legally, healthcare institutions are taken responsible in case of error and there are standards must be respected by engineers<sup>2 3</sup>



- 2. ISO 13485:2016 Medical devices Quality management systems Requirements for regulatory purposes
- 3. <u>ISO 62304:2006 Medical device software Software life cycle processes</u>

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## MAIN RISKS OF FAILURE

### REALITY-DESIGN GAPS<sup>12</sup>



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1. Heeks (2006) – Health Information Systems:: Failure, success and improvisation

2. Masiero (2016) - The Origins of Failure: Seeking the Causes of Design-Reality Gaps

# **HOW TO DESIGN A AI-BASED HIS**

## A CONTINUOUS INTEGRATION PROCESS <sup>1</sup>

- **1.** Identify and prioritize a problem
- 2. Identify requirements for an AI product as a viable component of the solution
- **3.** Develop measures of outcomes and success of the AI product
- 4. Design a new optimal workflow to facilitate integration
- 5. Evaluate safety, effectiveness, and equity concerns of the AI product in the intended setting prior to clinical use
- 6. Execute AI product rollout, workflow integration, communication, education, and scaling
- 7. After operationalization, monitor and maintain the AI product and impacted ecosystem
- 8. Update or decommission the AI product and impacted ecosystem

![](_page_10_Picture_12.jpeg)

## **ETHICS OF ALGORITHMS**

SOME PRINCIPLES <sup>1 2 3</sup>

![](_page_11_Picture_2.jpeg)

- Loyalty Principle
- Vigilance/Reflexivity Principle
- Autonomy Principle
- Justice Principle
- Transparency Principle

Le Serment Holberton-turing <sup>3</sup>

![](_page_11_Picture_9.jpeg)

<sup>1.</sup> https://www.cnil.fr/en/algorithms-and-artificial-intelligence-cnils-report-ethical-issues

<sup>2.</sup> https://www.cnil.fr/en/ai-systems-compliance-other-guides-tools-and-best-practices

<sup>3. &</sup>lt;u>https://www.holbertonturingoath.org/</u>

# **BIOMEDICAL ETHICS**

### A LARGE LITTERATURE <sup>1 2 3 4 5</sup>

![](_page_12_Picture_2.jpeg)

- Non-maleficence Principle
- Beneficence Principle
- Autonomy Principle
- Justice Principle

- 1. Miles (2004) The Hippocratic Oath and the Ethics of Medicine
- 2. Beauchamp and Childress (2013) Principles of Biomedical Ethics
- 3. <u>Cook (2020) Introduction to Biomedical Ethics</u>
- 4. Ferretti et al. (2020) Big Data, Biomedical Research, and Ethics Review: New Challenges for IRBs
- 5. Gomez-Virseda, Maeseneer and Gastmans (2019) Relational autonomy: what does it mean and how is it used in end-of-life care? A systematic review of argument-based ethics literature

# **TRANSPARENCY / EXPLICABILITY**

### HOW MUCH CAN WE TRUST AI?<sup>1234</sup>

Why this result and not another one?

Understandability

Al should be based on notions known by physicians

#### Interpretability

Physicians must have all the information to interpret Al's results without bias

In which situation this AI is good or not? 

How much can I trust this AI and its results?

#### Traceability

We must be able to trace back the context and the actions which conducted to a result

#### **Revisability**

We must be able to take into account physicians' feedbacks

Gunning and Aha (2019) – DARPA's Explainable Artificial Intelligence (XAI) Program

- Berredo-Arrieta et al. (2020) Explainable Artificial Intelligence (XAI): Concepts, taxonomies, opportunities and challenges toward responsible AI
- Mueller et al. (2019) Explanation in Humain-AI Systems: A Literature Meta-Review, Synopsis of Key Ideas and Publications, and Bibliography for Explainable AI
- Richard et al. (2020) Transparency of Classification Systems for Clinical Decision Support

![](_page_13_Picture_17.jpeg)

How to correct Al in case of error?

## **PRACTICAL WORKS**

DESIGNING AN AI-BASED HIS

![](_page_14_Picture_2.jpeg)

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## **DESIGNING AN AI-BASED HIS**

### USE CASE: PATIENT TRIAGE IN EMERGENCY SERVICES

• Your role: engineers of health information systems

• Your goal: designing an AI-based HIS for emergency departments to simplify/automatize patient triage

• At your disposal: a dataset and a notebook <u>https://github.com/a-t-richard/AI-Responsibility-in-Healthcare</u>

## **MERCI**

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