ALGORITHMS IN HEALTHCARE CONTEXTS

ETHICS AND RESPONSIBLITIES

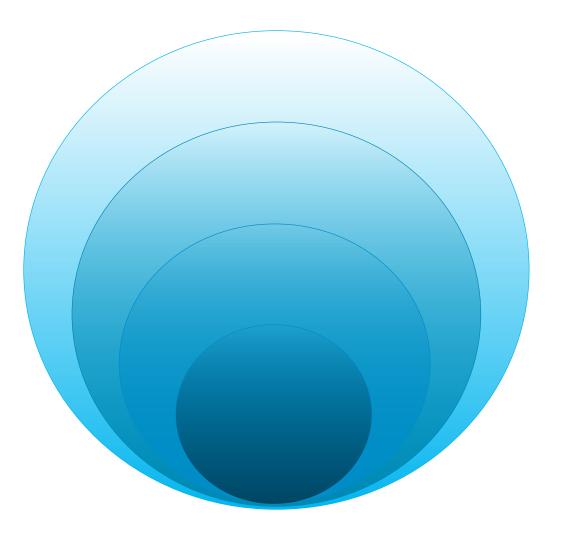


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DEFINITIONS

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 softwares¹

Machine Learning:

Sub-domain of artificial intelligence dedicated to create algorithms able to learn from data how to perform a task²

Deep Learning:

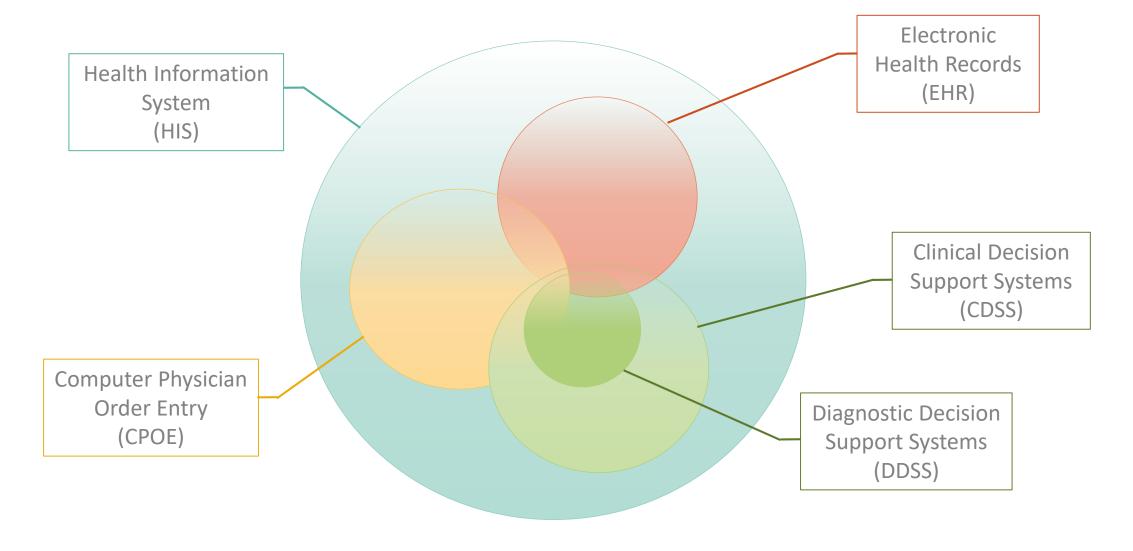
Sub-domain of machine learning dedicated to multi-layer artificial neural networks³



- 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

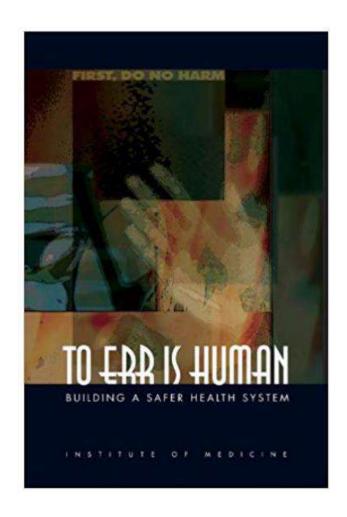
HEALTH INFORMATION SYSTEMS 1



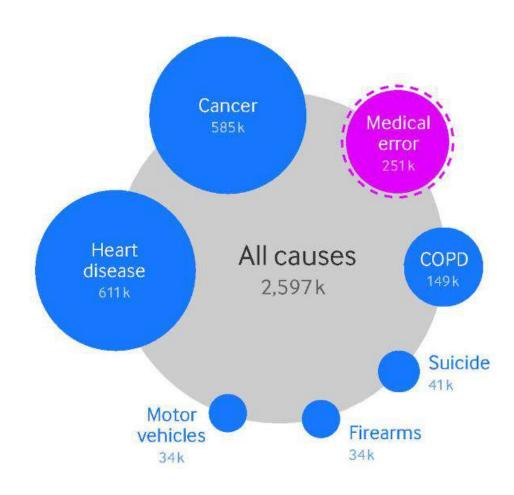


WHY DEVELOPING HIS?

TACKLE MEDICAL ERRORS







The third cause of death in the US in 2013 ²

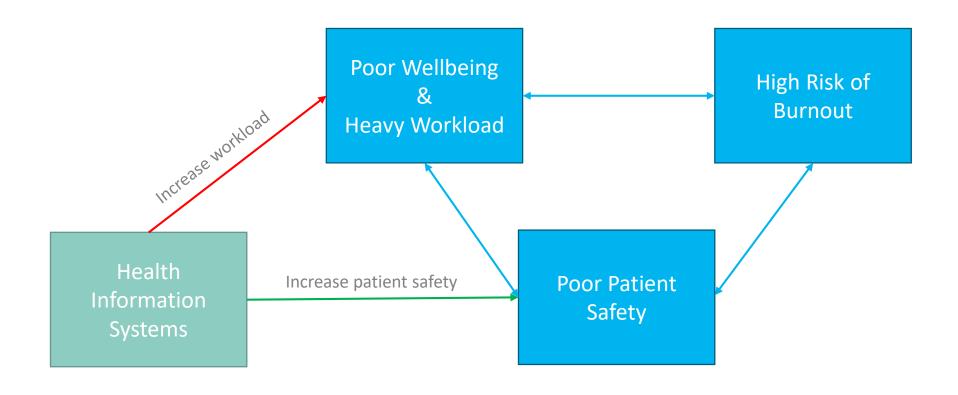


^{1. &}lt;u>Donaldson et al. (2000) – To err is human: building a safer health system</u>

[.] 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 1 2 3 4



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



LEGAL FRAMEWORK

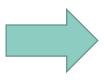
ISO STANDARDS



ISO 13485:

Quality management systems & Requirements for regulatory purposes

https://www.iso.org/standard/59752.html



Applicable to AI? 123



ISO 62304:

Medical device software & Software life cycle processes

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



Under development:

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



ISO 14971:

Application of risk management to medical devices

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



ISO 62366:

Application of usability engineering to medical devices

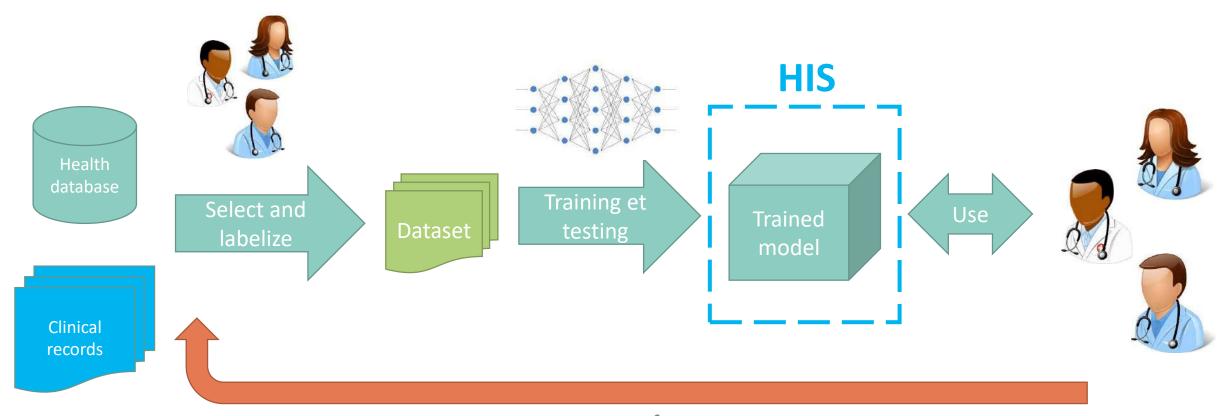
https://www.iso.org/standard/63179.html

- 1. O'Sullivan et al. (2018) Legal, regulatory, and ethical frameworks for development of standards in artificial intelligence (AI) and autonomous robotic surgery
- . Zhao (2019) Improving Social Responsibility of Artificial Intelligence by Using ISO 2600
- . 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 ¹

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

Loss of physicians' skills and know-how 2 3

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 ⁴

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



^{2. &}lt;u>Tsai, Fridsma and Gatti (2003) - Computer decision support as a source of interpretation error: the case of electrocardiograms</u>



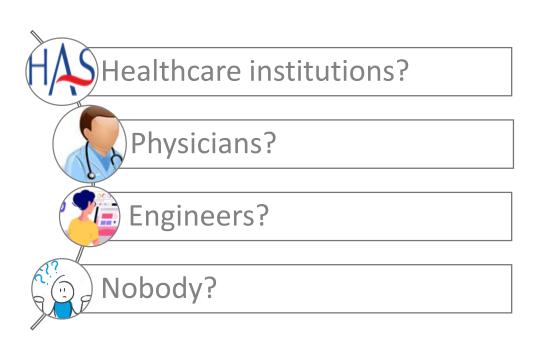
B. Povyakalo et al. (2013) – How to discriminate between Computer-Aided and Computer-Hindered Decisions: A Case study in Mammography

^{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 Al-based HIS, and this use conduct to medical error, who is responsible?





There is social pressure on physicians who use AI-based HIS ¹



Legally, healthcare institutions are taken responsible in case of error and there are standards must be respected by engineers²



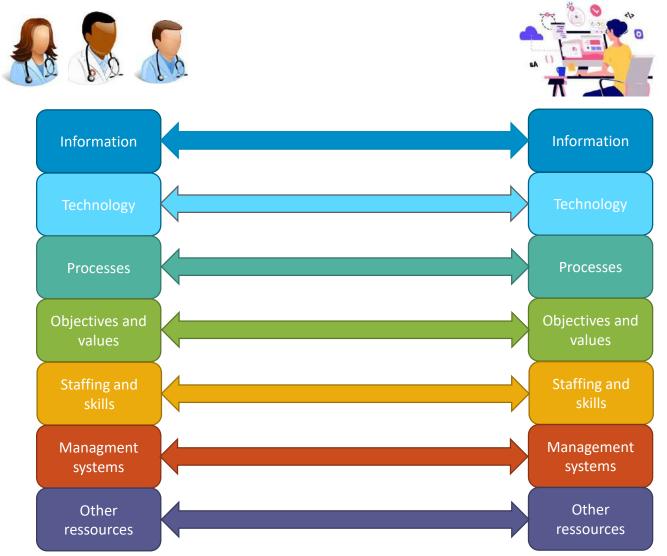
^{1. &}lt;u>Itani, Lecron and Fortemps (2019) – Specifics of medical data mining for diagnosis aid: A survey</u>

^{2. &}lt;u>ISO 13485:2016 – Medical devices — Quality management systems — Requirements for regulatory purposes</u>

^{3. &}lt;u>ISO 62304:2006 – Medical device software — Software life cycle processes</u>

MAIN RISKS OF FAILURE

REALITY-DESIGN GAPS 1 2



^{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 1

- 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



ETHICS OF ALGORITHMS

SOME PRINCIPLES 123



Le Serment Holberton-turing ³

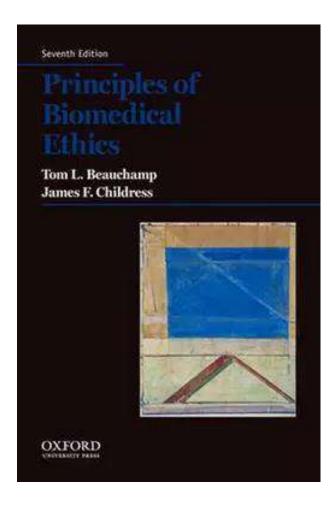
- Loyalty Principle
- Vigilance/Reflexivity Principle
- Autonomy Principle
- Justice Principle
- Transparency Principle



- 1. https://www.cnil.fr/en/algorithms-and-artificial-intelligence-cnils-report-ethical-issues
- 2. https://www.cnil.fr/en/ai-systems-compliance-other-guides-tools-and-best-practices
- 3. https://www.holbertonturingoath.org/

BIOMEDICAL ETHICS

A LARGE LITTERATURE 1 2 3 4 5



- 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. Cook (2020) Introduction to Biomedical Ethics
- 4. Ferretti et al. (2020) Big Data, Biomedical Research, and Ethics Review: New Challenges for IRBs
- 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? 1 2 3 4



• Why this result and not another one?

Understandability

Al should be based on notions known by physicians



How much can I trust this AI and its results?

Interpretability

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

In which situation this AI is good or not?

Traceability

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

• How to correct AI in case of error?

Revisability

We must be able to take into account physicians' feedbacks

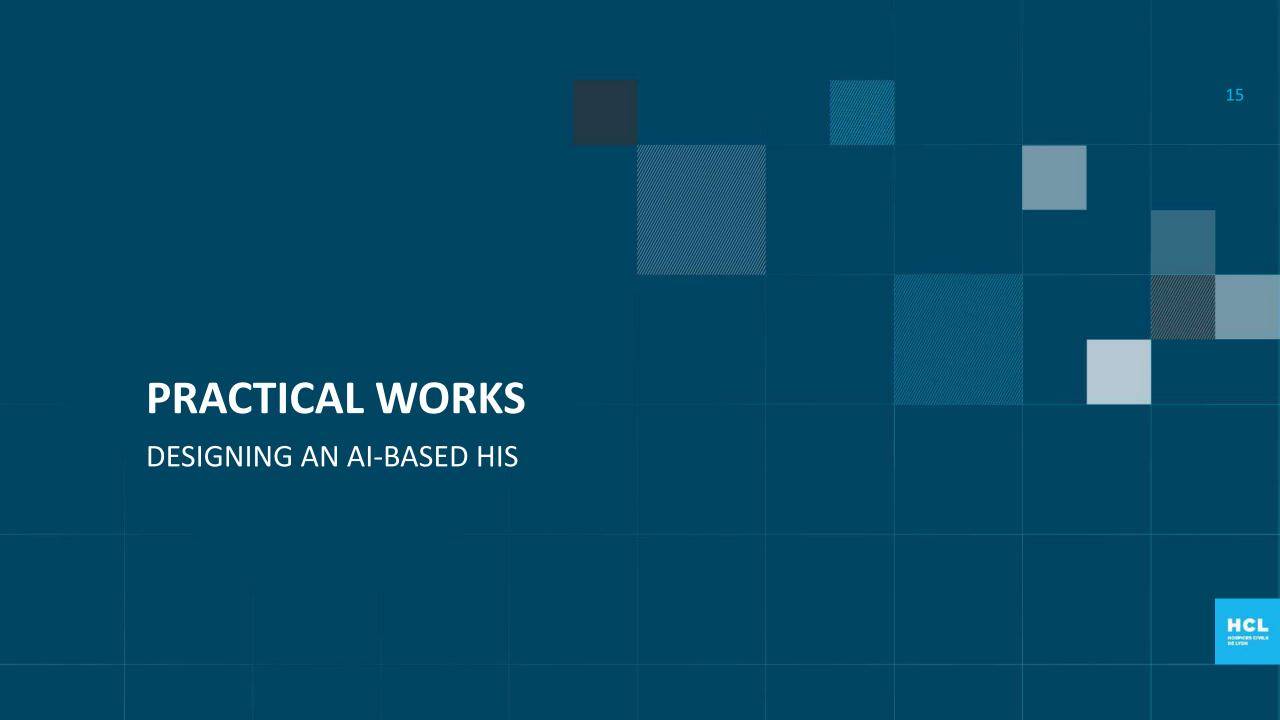


^{1.} Gunning and Aha (2019) – DARPA's Explainable Artificial Intelligence (XAI) Program

^{2.} Berredo-Arrieta et al. (2020) - Explainable Artificial Intelligence (XAI): Concepts, taxonomies, opportunities and challenges toward responsible Al

^{3.} Mueller et al. (2019) - Explanation in Humain-Al Systems: A Literature Meta-Review, Synopsis of Key Ideas and Publications, and Bibliography for Explainable Al

Richard et al. (2020) – Transparency of Classification Systems for Clinical Decision Support



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
https://github.com/a-t-richard/AI-Responsibility-in-Healthcare



MERCI

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