PennState
Dickinson Law

Ethical & Legal Considerations for Biomedical AI

BMI 702 – April 18, 2024

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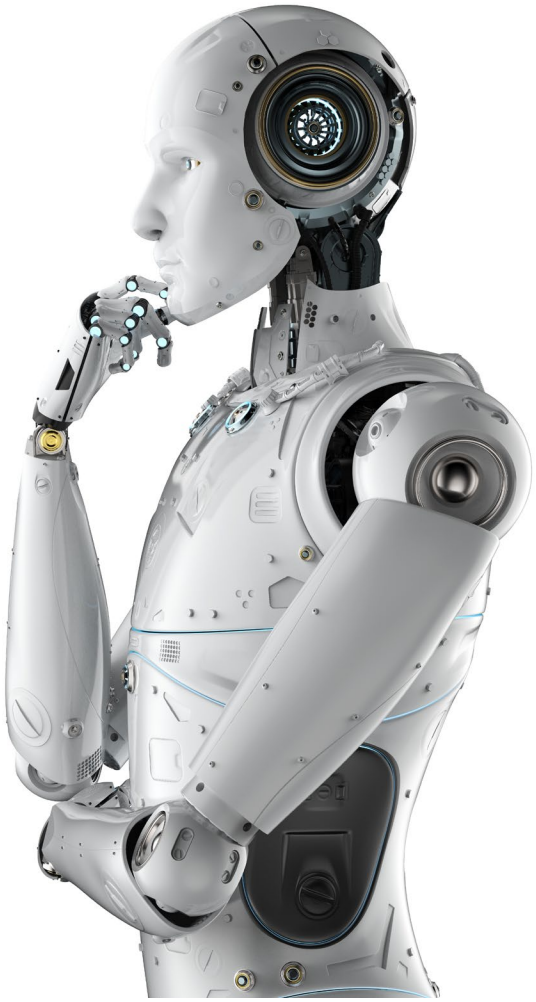
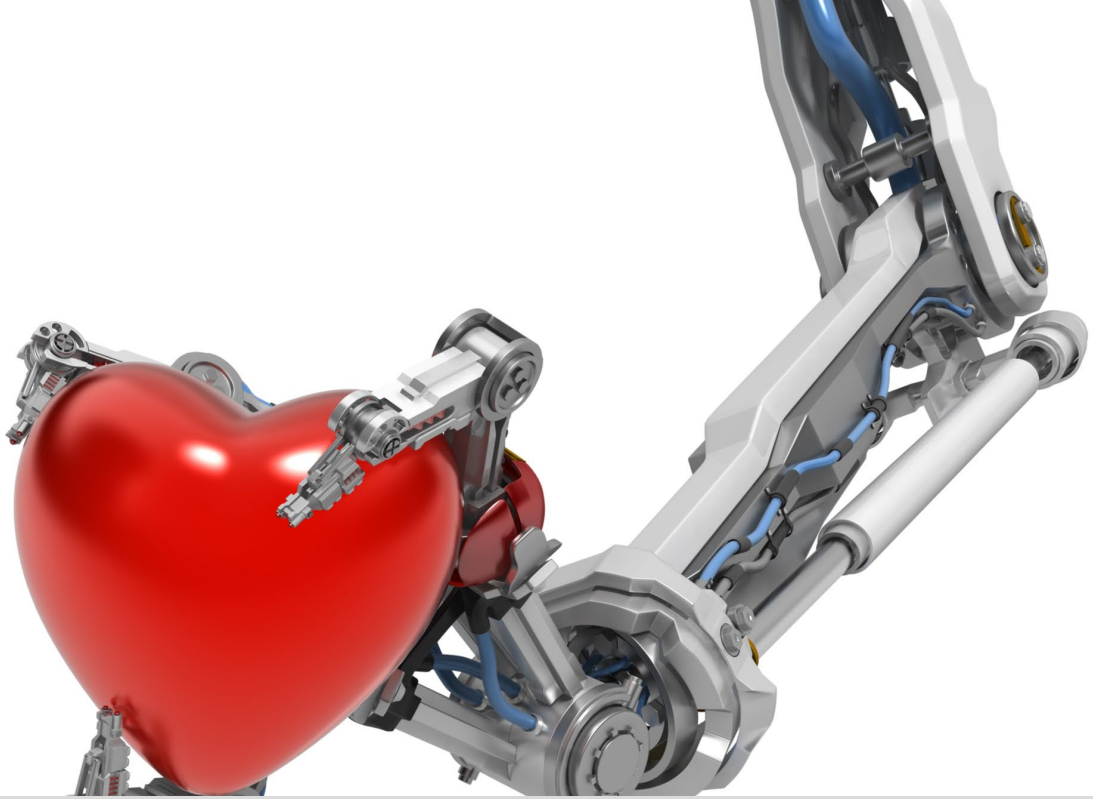
Outline

- Ethical Frameworks
- Data Privacy
- Regulation of AI/ML
- Liability



Ethical Frameworks



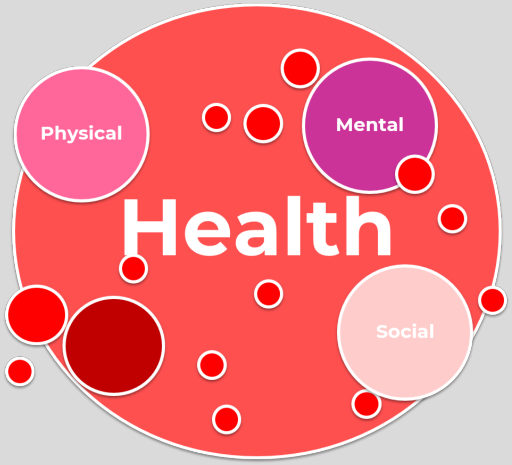
1.

What Is Health AI Ethics?

Health AI Ethics

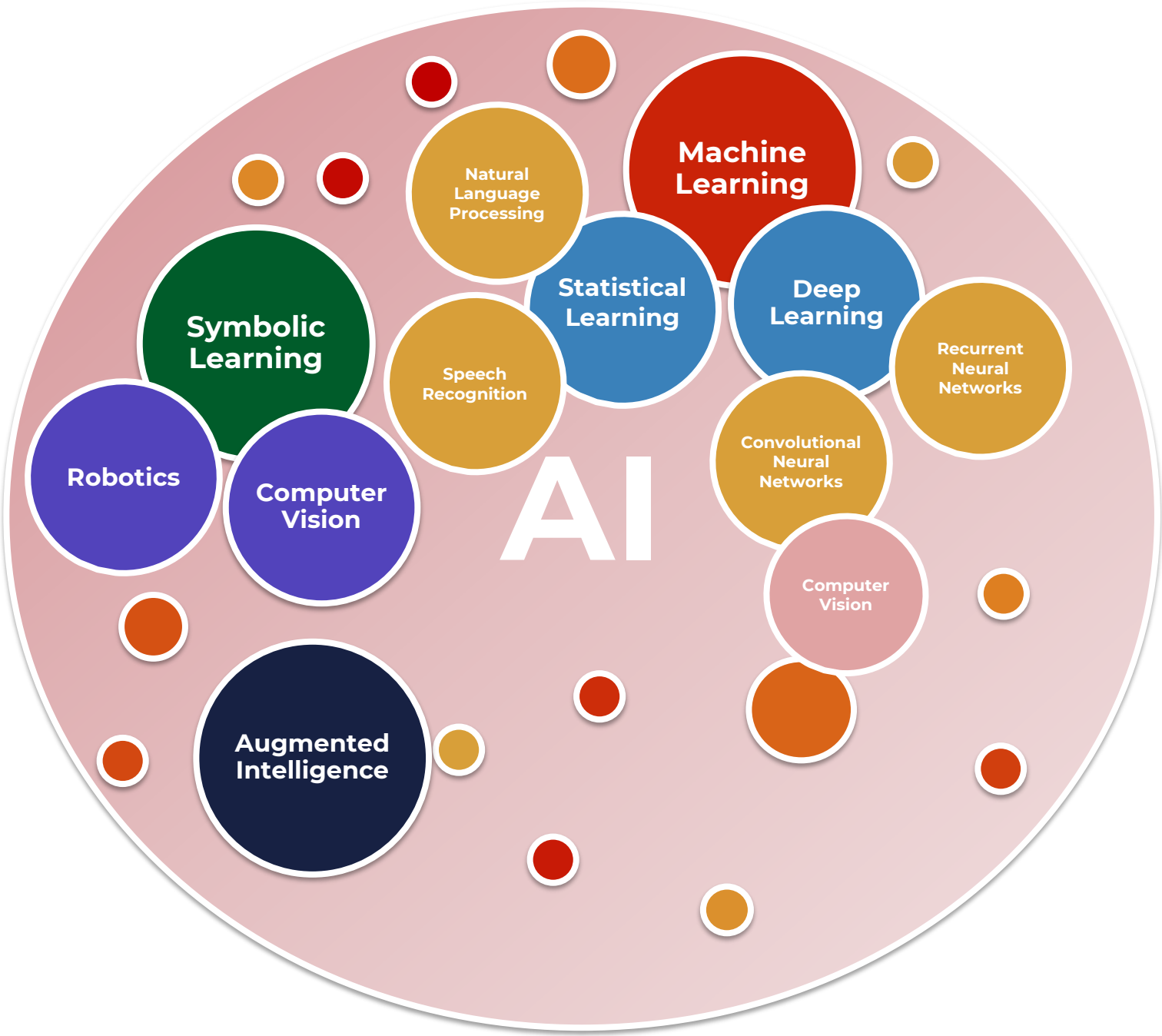
Application and analysis of ethics to contexts in health in which AI is involved

Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).



A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

World Health Organization. Constitution. https://www.who.int/about/governance/constitution.


AI
Machine Learning
Natural Language Processing
Statistical Learning
Deep Learning
Symbolic Learning
Speech Recognition
Recurrent Neural Networks
Convolutional Neural Networks
Robotics
Computer Vision
Computer Vision
Augmented Intelligence

Ethics

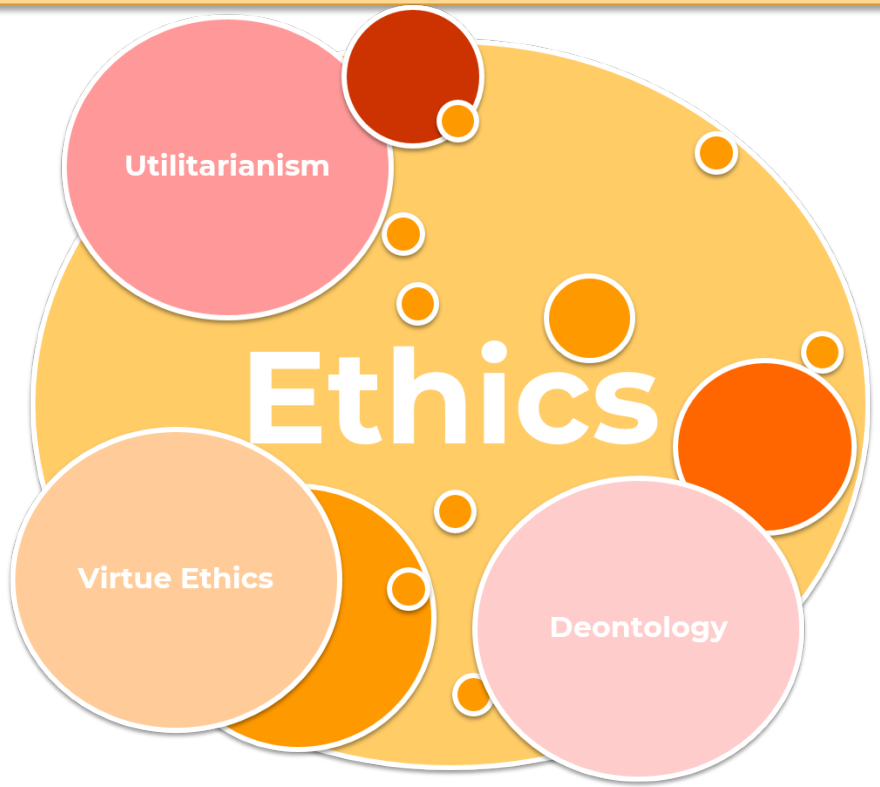
Normative Ethics

Metaethics

Applied Ethics

Normative Ethics

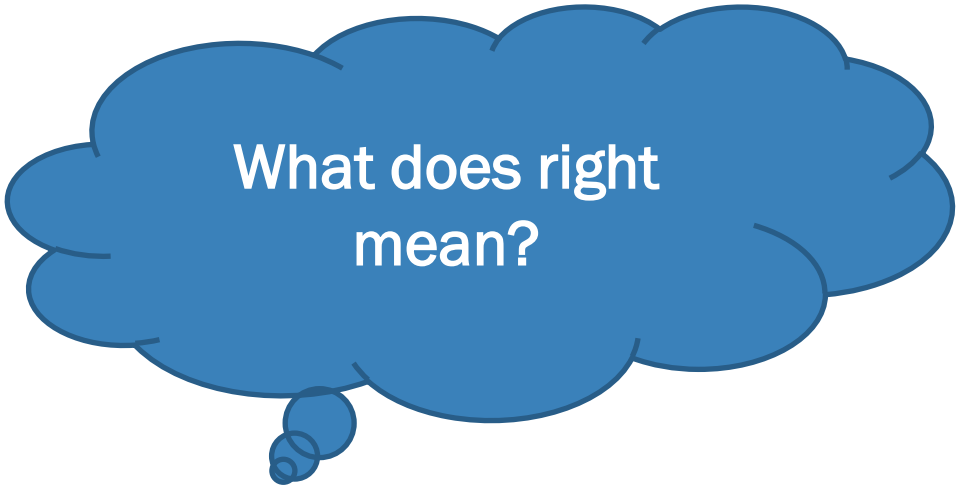
- Tries to answer questions about the right way to act.



Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).

Metaethics

- Addresses questions about the nature of right and wrong



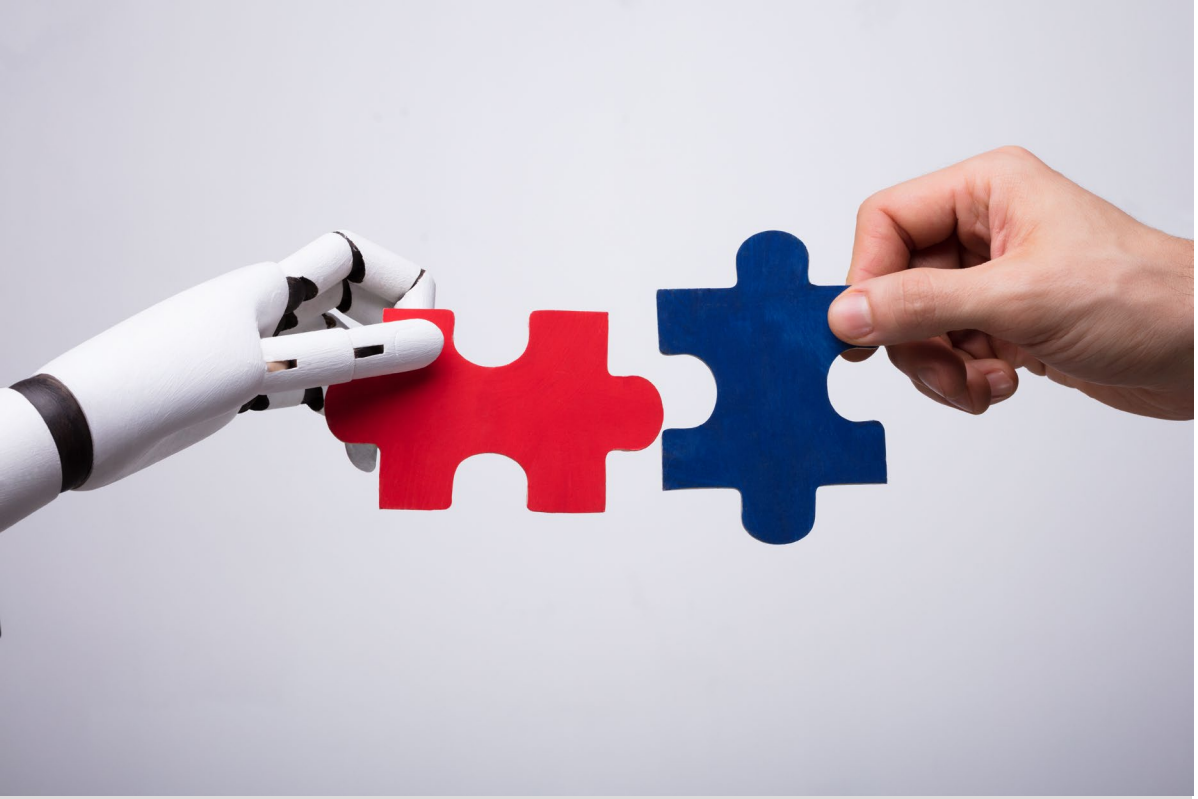
Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).

Applied Ethics

- Deals with applying ethical theories or principles to specific, real-life issues

Principles of Biomedical Ethics by James F. Childress and Tom L. Beauchamp

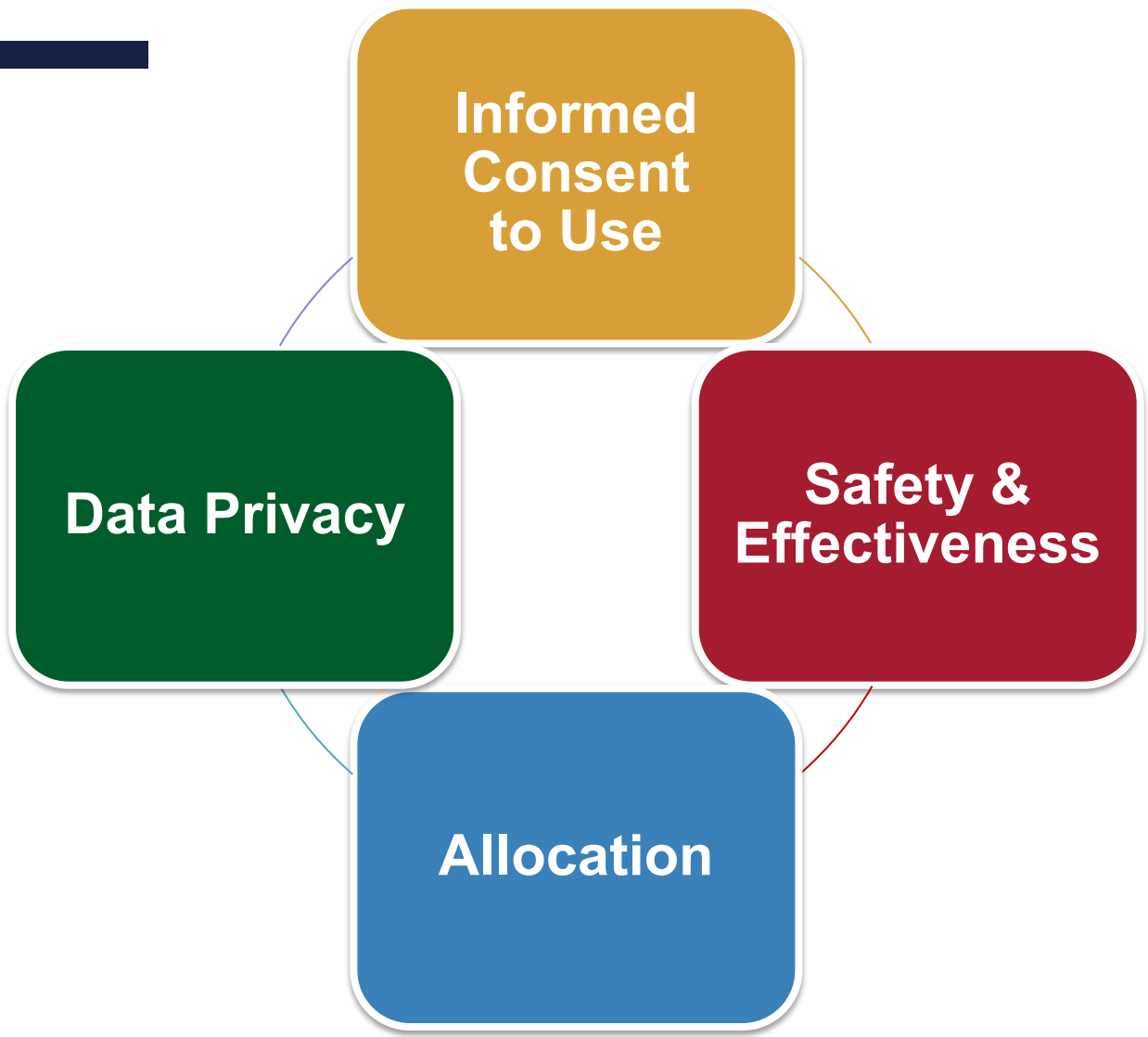
Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).



2.

Ethical Issues

Ethical Issues



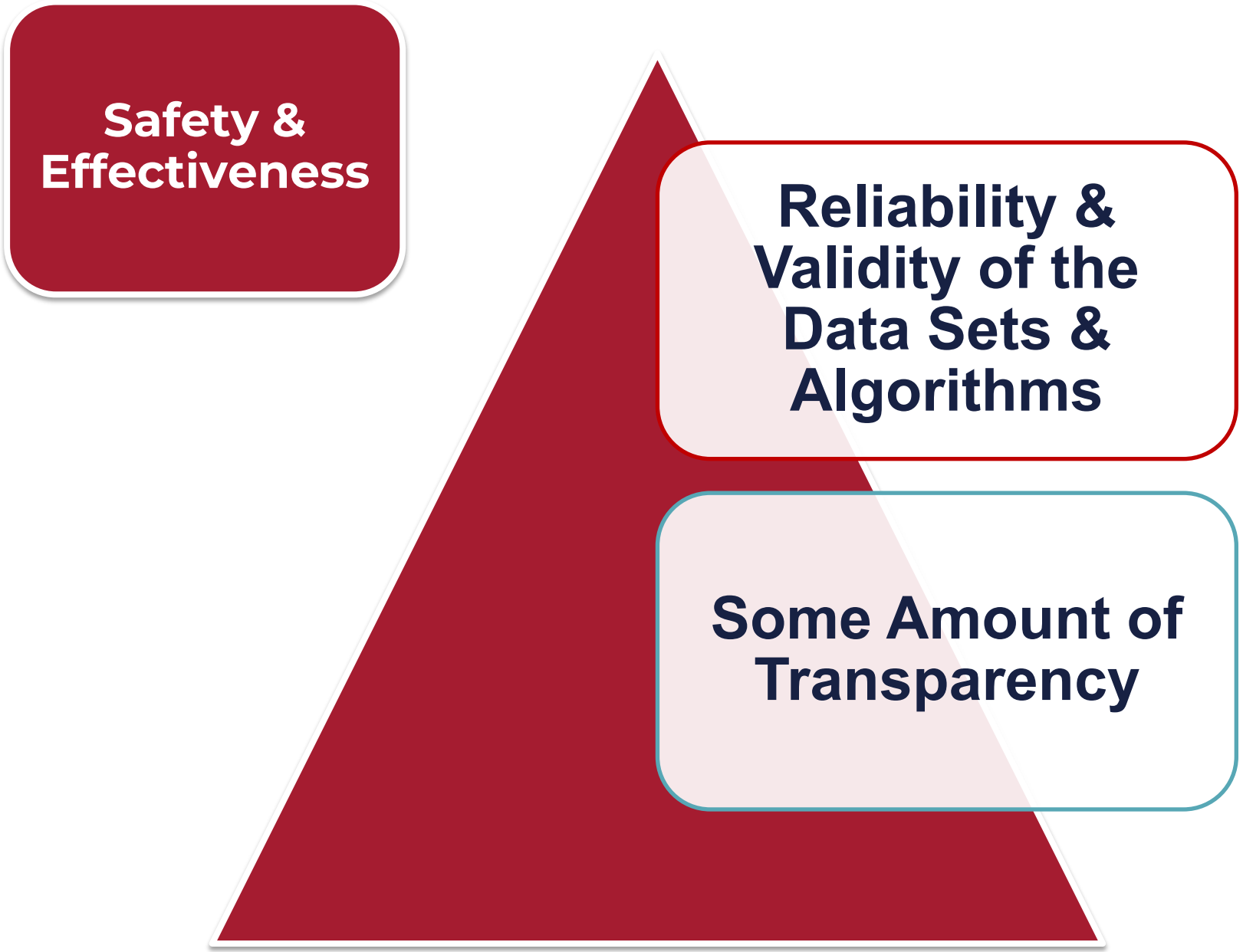
Informed Consent to Use

Need to examine under what circumstances (if at all) the **principles of informed consent** should be deployed in the clinical AI space.

Especially challenging to answer in cases where the AI operates using **"black-box" algorithms**.

Health AI apps & chatbots raise questions about **user agreements** & their relationship to informed consent.

Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).



Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).

Safety & Effectiveness

Reliability & Validity of the Data Sets & Algorithms

Training Data

Algorithmic

Contextual

Unconscious

Ethics by Design

Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).

Timo Minssen, Sara Gerke, Mateo Aboy, Nicholson Price & I. Glenn Cohen, Regulatory Responses to Medical Machine Learning, J. L. BIOSCI. lsaa002 (2020).

Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).

Sara Gerke, Timo Minssen, Helen Yu & I. Glenn Cohen, *Ethical and Legal Issues of Ingestible Electronic Sensors*, 2 NATURE ELECTRON. 329 (2019).

Safety & Effectiveness

Some Amount of Transparency

E.g., shortcomings of the software

Trust

Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).

Allocation

SCIENCE

WHAT HAPPENS WHEN AN ALGORITHM CUTS YOUR HEALTH CARE

By Colin Lecher | @colinlecher | Mar 21, 2018, 9:00am EDT

Illustrations by William Joel; Photography by Amelia Holowaty Krales

SHARE

For most of her life, Tammy Dobbs, who has cerebral palsy, relied on her family in Missouri for care. But in 2008, she moved to Arkansas,

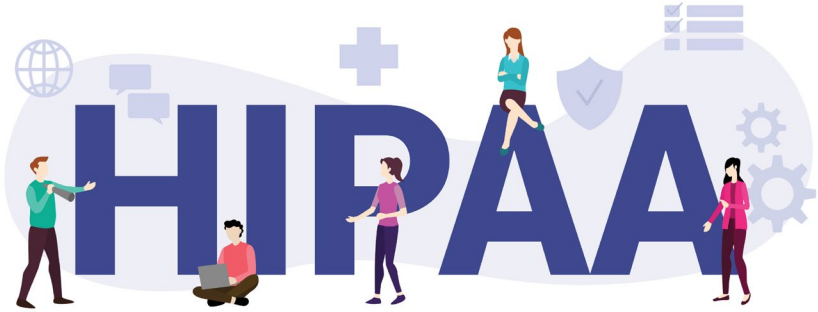
Photo Credit: https://www.theverge.com/2018/3/21/17144260/healthcare-medicaid-algorithm-arkansas-cerebral-palsy

Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, Advances in Health Sciences Education 26, 1447–1458 (2021).

Case Problem

The Patient With Diabetes

Data Privacy



Health Insurance Portability and Accountability Act

Data Triangulation

Protected Health Information (PHI)

generated by

Covered Entities

or their

Business Associates

Individually identifiable health information

- **Health Plans**
- **Health Care Clearinghouses**
- **Health Care Providers**

Person or entity that performs certain functions or activities on behalf of, or provides services to, a covered entity that involve the use or disclosure of PHI

share

BAA

De-Identified Health Information e.g., removal of 18 identifiers

Health Information Generated by Entities Not Covered by HIPAA



Sara Gerke, Timo Minssen & I. Glenn Cohen, *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* Artificial Intelligence in Healthcare 295 (Adam Bohr & Kaveh Memarzadeh eds., Elsevier 2020).

Data Privacy

New Legal Developments to Protect Privacy

- Has been applied since **25 May 2018 in all EU Member States**
- **Protects fundamental rights and freedoms of natural persons** and in particular their **right to the protection of personal data** (Art. 1(2))
- **Broad material & territorial scope** (Arts. 2, 3)
  - **Impact on U.S. entities** (e.g., processing activities are related to the offering of goods or services to data subjects in the EU)

Data Privacy

New Legal Developments to Protect Privacy in the U.S.

Photo Credit: https://redcloveradvisors.com

Became effective on **January 1, 2020**

Grants various rights to California residents with regard to **personal information that is held by businesses**

Sara Gerke & Delaram Rezaeikhonakdar, *Privacy Aspects of Direct-To-Consumer Artificial Intelligence/Machine Learning Health Apps*, Intelligence-Based Medicine 6 (2022) 100061

Case Problem

The Patient With Diabetes – Part 2

Regulation of AI/ML

Regulation of AI/ML

Medical Device Definition, FDCA Section 201(h)(1)

(…) an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

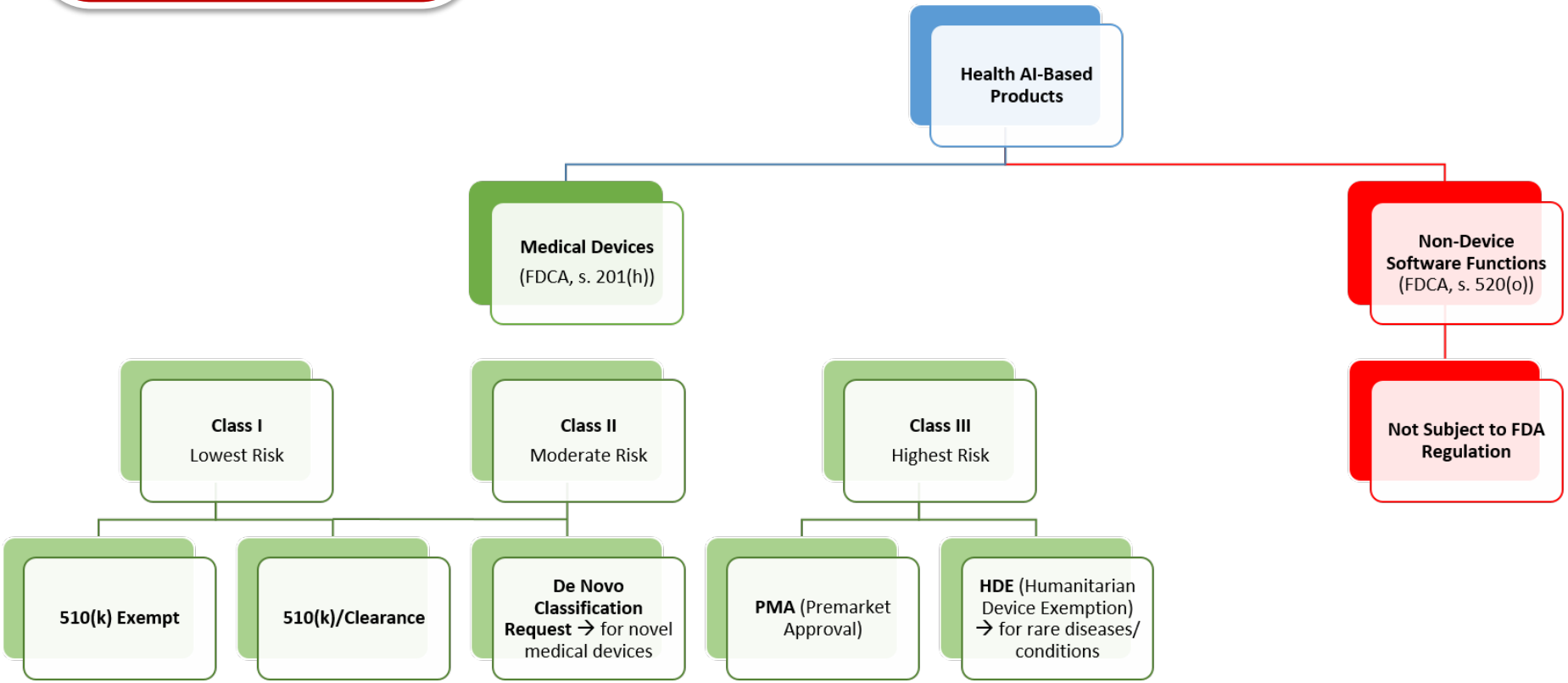
(B) **intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man** or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals **and which is not dependent upon being metabolized for the achievement of its primary intended purposes**. The term "device" does not include software functions excluded pursuant to section 520(o).

Regulation of AI/ML

Regulatory Pathways



Adapted from Sara Gerke et al., *Regulatory, Safety, and Privacy Concerns of Home Monitoring Technologies During COVID-19*, 26 NATURE MED. 1176 (2020).

Regulation of AI/ML

Non-Device Software Functions, FDCA Section 520(o)

1. For administrative support of a health care facility

2. For maintaining or encouraging a healthy lifestyle

3. To serve as electronic patient records

4. For transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results

5. To support certain clinical decisions

Regulation of AI/ML

Update Problem

AI/ML-Based SaMD

(**A**rtificial **I**ntelligence/**M**achine **L**earning-**B**ased **S**oftware **a**s a **M**edical **D**evice)


IMDRF/SaMD WG/N10FINAL:2013

IMDRF International Medical Device Regulators Forum

Final Document

Title:	Software as a Medical Device (SaMD): Key Definitions
Authoring Group:	IMDRF SaMD Working Group
Date:	9 December 2013

Software intended to be used for **one or more medical purposes** that perform these purposes **without being part of a hardware medical device**.

Those purposes that are **intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions.**

FDA

FDA (2019) Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD), https://www.fda.gov/media/122535/download.

Regulation of AI/ML

Update Problem

"Locked" Algorithm

"Adaptive" Algorithm

FDA

An algorithm that provides **the same result** each time **the same input is applied to it** and **does not change with use**.

An algorithm that **may change** as it is **applied to new data**.

FDA (2019) Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD), https://www.fda.gov/media/122535/download.

Regulation of AI/ML

Update Problem

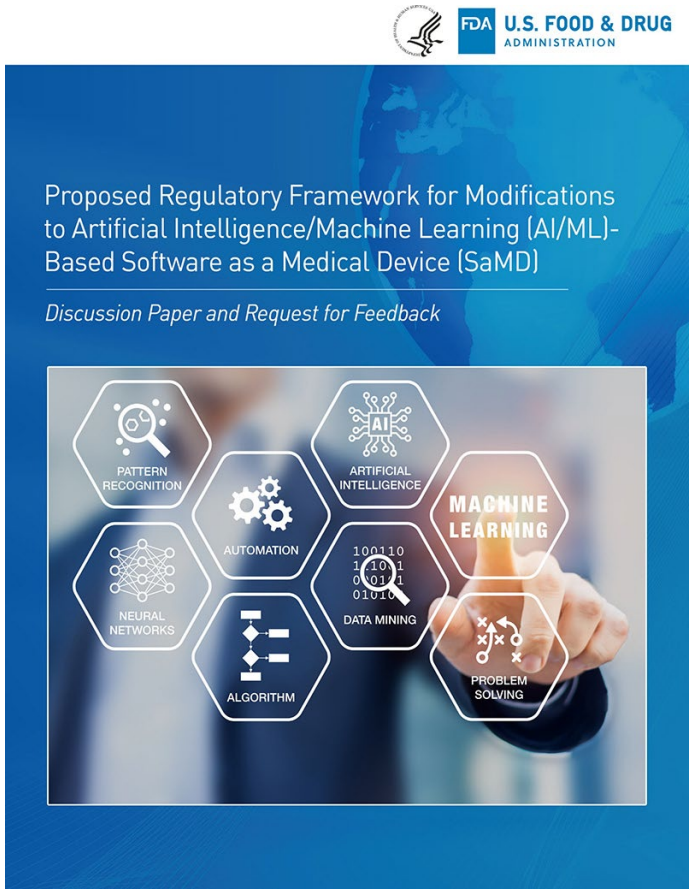


Photo Credit: https://www.fda.gov/media/122535/download

Total Product Lifecycle (TPLC) Regulatory Approach

Predetermined Change Control Plan

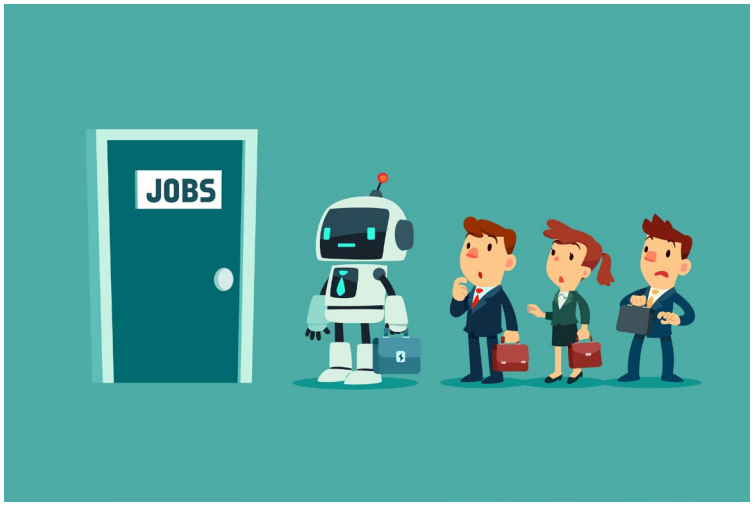
Continuous Risk Monitoring

Focus on new risks due to AI/ML characteristics.

Boris Babic, Sara Gerke, Theodoros Evgeniou & I. Glenn Cohen, *Algorithms on Regulatory Lockdown in Medicine: Prioritize Risk Monitoring to Address the "Update Problem"*, 366 SCIENCE 1202 (2019).

Regulation of AI/ML → **System View**

- Regulators like the FDA need to **widen their scope** from evaluating medical AI/ML-based products to **assessing systems**.



Sara Gerke, Boris Babic, Theodoros Evgeniou & I. Glenn Cohen, *The Need for a System View to Regulate Artificial Intelligence/Machine Learning-Based Software as Medical Device*, 3 NPJ DIGIT. MED. Article number: 53 (2020).

Regulation of AI/ML

The FDA's New Action Plan

- **Further developing the proposed regulatory framework**, including issuing draft guidance on a predetermined change control plan
- Supporting the development of **good machine learning practices** to evaluate and improve machine learning algorithms
- Fostering a **patient-centered approach**, including device transparency to users
- Developing methods to **evaluate and improve machine learning algorithms**; and
- Advancing **real-world performance monitoring** pilots.

https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

Regulation of AI/ML

Contains Nonbinding Recommendations

Draft – Not for Implementation

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on April 3, 2023.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial

U.S. FOOD & DRUG ADMINISTRATION | Health Canada Santé Canada | Medicines & Healthcare products Regulatory Agency

Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles

October 2023

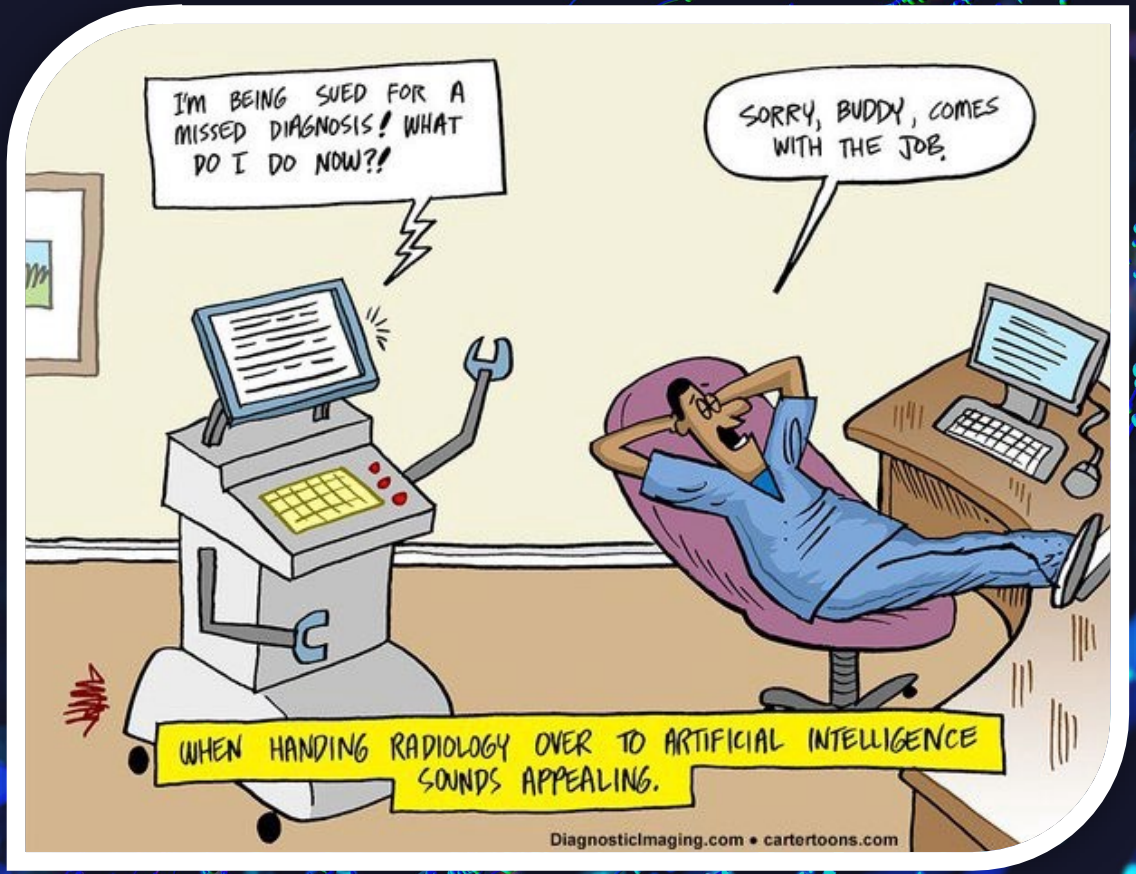
In 2021, the U.S. Food and Drug Administration (FDA), Health Canada, and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) jointly identified 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP). GMLP supports the development of safe, effective, and high-quality artificial intelligence/machine learning technologies that can learn from real-world use and, in some cases, improve device performance.

In this document, FDA, Health Canada, and MHRA jointly identified 5 guiding principles for predetermined change control plans. These principles draw upon the overarching GMLP guiding principles, in particular principle 10, which states that deployed models are monitored for performance and re-training risks are managed.

Advancements in digital health technologies include artificial intelligence/machine learning-enabled medical devices (MLMD). Regulatory expectations that are aligned with best practices for development and change management, such as those described in the GMLP Guiding Principles, can help to support the quality of such devices. Ultimately, this can lead to patient benefits such as earlier access to innovative technologies or more accurate diagnoses.

https://www.fda.gov/medical-devices/software-medical-device-samd/predetermined-change-control-plans-machine-learning-enabled-medical-devices-guiding-principles

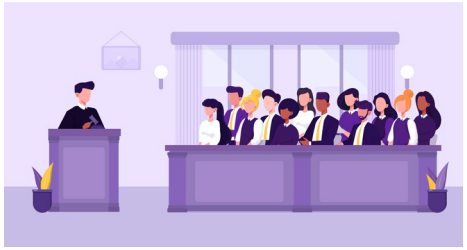
Liability


I'm BEING SUED FOR A MISSED DIAGNOSIS! WHAT DO I DO NOW?!
SORRY, BUDDY, COMES WITH THE JOB.
WHEN HANDING RADIOLOGY OVER TO ARTIFICIAL INTELLIGENCE SOUNDS APPEALING.
DiagnosticImaging.com • cartertoons.com

Examples of Potential Legal Outcomes Related to AI Use in Clinical Practice

Scenario	AI recommendation	AI accuracy	Physician action	Patient outcome	Legal outcome (probable)
1	Standard of care	Correct	Follows	Good	No injury and no liability
2			Rejects	Bad	Injury and liability
3		Incorrect (standard of care is incorrect)	Follows	Bad	Injury but no liability
4			Rejects	Good	No injury and no liability
5	Nonstandard care	Correct (standard of care is incorrect)	Follows	Good	No injury and no liability
6			Rejects	Bad	*Injury but no liability*
7		Incorrect	Follows	Bad	*Injury and liability*
8			Rejects	Good	No injury and no liability

W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Potential Liability for Physicians Using Artificial Intelligence* 322 JAMA 1765 (2019).



W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *How Much Can Potential Jurors Tell Us about Liability for Medical Artificial Intelligence?*, 62 THE JOURNAL OF NUCLEAR MEDICINE 15 (2021).

Generative AI

Opinion

VIEWPOINT

AI IN MEDICINE

Generative AI in Health Care and Liability Risks for Physicians and Safety Concerns for Patients

Mindy Duffourc, JD, BA
Project CLASSICA: Validating AI in Classifying Cancer in Real-Time Surgery, Penn State Dickinson Law, Carlisle, Pennsylvania.

Sara Gerke, Dipl-Jur Univ, MA
Penn State Dickinson Law, Carlisle, Pennsylvania.

Viewpoint

Generative artificial intelligence (AI) is a quickly emerging subfield of AI that can be trained with large data sets to create realistic images, videos, text, sound, 3-dimensional models, virtual environments, and even drug compounds. It has gained more attention recently as chatbots such as OpenAI's ChatGPT or Google's Bard display impressive performance in understanding and generating natural language text. Generative AI is being heralded in the medical field for its potential to ease the long-lamented burden of medical documentation by generating visit notes, treatment codes, and medical summaries. Physicians and patients might also turn to generative AI to answer medical questions about symptoms, treatment recommendations, or potential diagnoses.[1] While these tools may improve patient care, the liability implications of using AI to generate health information are still in flux. To date, no court in the United States has considered the question of liability for medical injuries caused by relying on AI-generated informa-

The ability of black-box generative AI systems to provide users with quick health-related information raises the question of whether, and if so how, health care professionals, such as physicians, and patients should use this technology. To answer this question, it is important to understand the potential liability risks for physicians using generative AI in health care and the risks for patients seeking medical advice from such tools.

Liability Risks for Physicians Using Generative AI

Crucially, no generative AI systems, including ChatGPT and Bard, have been reviewed by the US Food and Drug Administration (FDA) so far. These systems could trigger FDA review if they are "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease" and do not fall under a medical device exception laid out in the Federal Food, Drug, and Cosmetic Act (see sections 201[h][1] and 520[o]).[3] It currently appears that while ChatGPT

ferential diagnoses in response
f symptoms, it also warns users
edical professional. But what if
is a medical professional? Can
assist them in making medical
s?
nAI's terms of use warn that
can "result in incorrect [o]ut-
does not accurately reflect real
places, or facts."[4] ChatGPT also
at "it can occasionally produce
t answers...and may also occa-
produce harmful instructions or

You

Are you a medical device?

ChatGPT

No, I'm not a medical device. I'm an AI language model created by OpenAI, designed to assist with information retrieval, conversation, and various tasks like text generation and answering questions.

https://chat.openai.com/ (generated on April 14, 2024); Mindy Duffourc & Sara Gerke, ***Generative AI in Health Care and Liability Risks for Physicians and Safety Concerns for Patients***, 330 JAMA 313 (2023).

Ecosystem of Liability

- Physicians
- Hospital Systems
- AI Makers
- Payers

W. Nicholson Price II, Sara Gerke & I. Glenn Cohen, *Potential Liability for Physicians Using Artificial Intelligence* 322 JAMA 1765 (2019).

Recent Developments in the EU

EUROPEAN
COMMISSION

Brussels, 28.9.2022
COM(2022) 496 final

2022/0303 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on adapting non-contractual civil liability rules to artificial intelligence (AI Liability Directive)

(Text with EEA relevance)

{SEC(2022) 344 final} - {SWD(2022) 318 final} - {SWD(2022) 319 final} - {SWD(2022) 320 final}

https://commission.europa.eu/system/files/2022-09/1_1_197605_prop_dir_ai_en.pdf

EUROPEAN
COMMISSION

Brussels, 28.9.2022
COM(2022) 495 final

2022/0302 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on liability for defective products

(Text with EEA relevance)

{SEC(2022) 343 final} - {SWD(2022) 315 final} - {SWD(2022) 316 final} - {SWD(2022) 317 final}

https://single-market-economy.ec.europa.eu/system/files/2022-09/COM_2022_495_1_EN_ACT_part1_v6.pdf

Recent Developments in the EU

Decoding U.S. Tort Liability in Healthcare's Black-Box AI Era: Lessons from the European Union

Mindy Duffourc* & Sara Gerke**

27 STAN. TECH. L. REV. 1 (2024)

ABSTRACT

…opment of sophisticated artificial intelligence ("AI") tools in … new possibilities for improving medical treatment and …ently, such AI tools can perform a wide range of health- … specialized autonomous systems that diagnose diabetic …ral-use generative models like ChatGPT that answer users' …ions. On the other hand, significant liability concerns arise

https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4569698

npj | digital medicine

www.nature.com/npjdigitalmed

PERSPECTIVE OPEN

Check for updates

The proposed EU Directives for AI liability leave worrying gaps likely to impact medical AI

Mindy Nunez Duffourc[1,2] and Sara Gerke[1]✉

Two newly proposed Directives impact liability for artificial intelligence in the EU: a Product Liability Directive (PLD) and an AI Liability Directive (AILD). While these proposed Directives provide some uniform liability rules for AI-caused harm, they fail to fully accomplish the EU's goal of providing clarity and uniformity for liability for injuries caused by AI-driven goods and services. Instead, the Directives leave potential liability gaps for injuries caused by some black-box medical AI systems, which use opaque and complex reasoning to provide medical decisions and/or recommendations. Patients may not be able to successfully sue manufacturers or healthcare providers for some injuries caused by these black-box medical AI systems under either EU Member States' strict or fault-based liability laws. Since the proposed Directives fail to address these potential liability gaps, manufacturers and healthcare providers may have difficulty predicting liability risks associated with creating and/or using some potentially beneficial black-box medical AI systems.

npj Digital Medicine (2023)6:77 ; https://doi.org/10.1038/s41746-023-00823-w

https://www.nature.com/articles/s41746-023-00823-w

Thanks!

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