



M Northwestern Medicine®
Feinberg School of Medicine

Institute for Augmented
Intelligence in Medicine
presents:

Navigating the Legal Landscape of AI in Medicine

March 15, 2023

I.AIM's Mission

The mission of the Institute for Augmented Intelligence in Medicine is to bridge computational methods with human expertise to advance medical science and improve human health.

Welcome



Abel Kho, MD

Director, Institute for Public Health
and Medicine (IPHAM) - Center for
Health Information Partnerships
(CHIP)

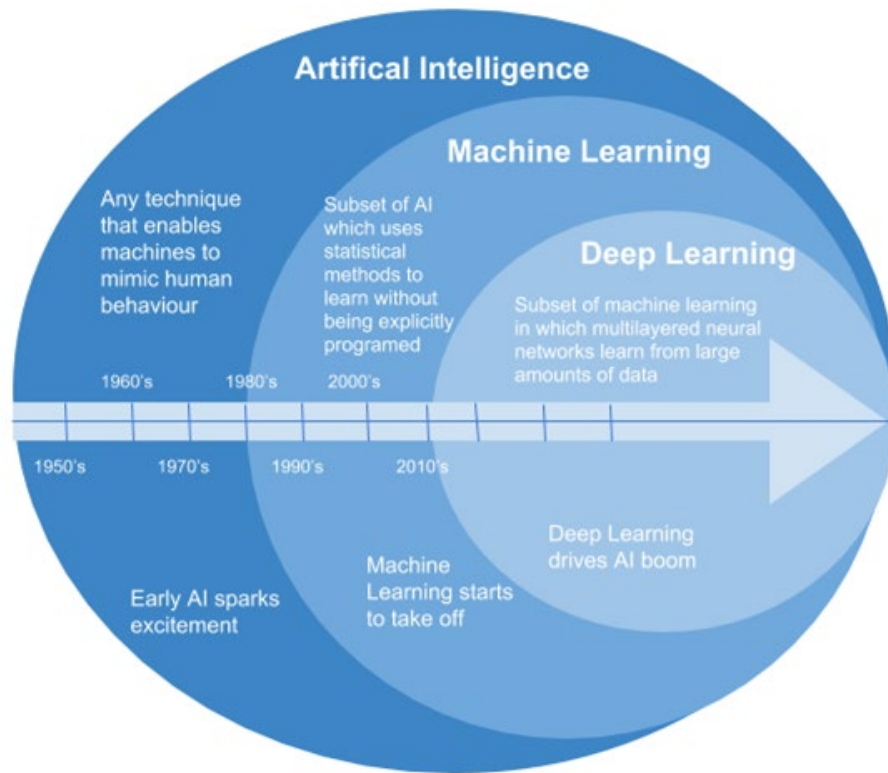
Director, Institute for Augmented
Intelligence in Medicine (I.AIM)

Introduction to Large Language Models and ChatGPT



Mohammad Hosseini, PhD
Postdoctoral Researcher, Preventive Medicine
Editor, *Journal of Accountability in Research*
Member, Global Young Academy

What Is AI



What Is a Search Engine?

As you would explain it to a 6-year-old



DuckDuckGo



What Is a Search Engine?

As you would explain it to a 6-year-old

A search engine is a system that mimics a **librarian** who shows us the whereabouts of information! It knows how to find sources very quickly based on our request.



DuckDuckGo



What is ChatGPT?

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Digital Chimera



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Digital Chimera



LLMs in healthcare

Possibilities seem endless, but ...



Speakers



Daniel W. Linna Jr., JD

Senior Lecturer & Director of Law and
Technology Initiatives

Northwestern Pritzker School of Law and
McCormick School of Engineering



Andrea Lee Linna, JD

Partner and Co-Lead of the Digital Health,
Technology and Innovation practice group at
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Legal Considerations for AI

1. AI technology and solutions are varied, which creates a wide range of facts and circumstances to address through compliance measures
2. Most applicable healthcare laws and regulations pre-date the development of AI
3. Adaption of the law to healthcare technology lags behind the pace of AI innovation

The closer the AI software recommendations or solutions come to (a) being the sole basis for a diagnosis or treatment or (b) black box technology that does not enable independent clinician review of the basis for the recommendation or solution, the greater the degree of risk and uncertainty concerning how to apply current laws

FDA - When Is AI Regulated as a Medical Device?

1. FDA defines a “device” as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article ... which is ... **intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease**”
 - Ask: What is the intended use of the AI?
2. The FDA excludes from the definition of a “device” certain software functions such as software that provides administrative support to a healthcare facility or is for maintaining or encouraging a healthy lifestyle and unrelated to diagnosis, cure, etc. of a disease
3. The FDA also exercises enforcement discretion when a product involves a technology that does not pose a risk to the safety of the users

FTC

- Federal Trade Commission Act (15 USC §45): FTC is “**empowered ... to ... prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce**”
- This would include the sale or use of - for example - racially biased algorithms

RESEARCH ARTICLE**ECONOMICS**

Dissecting racial bias in an algorithm used to manage the health of populations

Ziad Obermeyer^{1,2*}, Brian Powers³, Christine Vogeli⁴, Sendhil Mullainathan^{5*†}

Health systems rely on commercial prediction algorithms to identify and help patients with complex health needs. We show that a widely used algorithm, typical of this industry-wide approach and affecting millions of patients, exhibits significant racial bias: At a given risk score, Black patients are considerably sicker than White patients, as evidenced by signs of uncontrolled illnesses. Remedying this disparity would increase the percentage of Black patients receiving additional help from 17.7 to 46.5%. The bias arises because the algorithm predicts health care costs rather than illness, but unequal access to care means that we spend less money caring for Black patients than for White patients. Thus, despite health care cost appearing to be an effective proxy for health by some measures of predictive accuracy, large racial biases arise. We suggest that the choice of convenient, seemingly effective proxies for ground truth can be an important source of algorithmic bias in many contexts.

HIPAA

1. The Health Insurance Portability and Accountability Act (HIPAA) was enacted in 1996. Not drafted with AI in mind. As a result, we are left applying old law to new technology.
2. Protected Health Information (“PHI”)
 - a. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past present or future payment for the provision of health care to an individual
 - b. Either (i) identifies the individual; or (ii) with respect to which there is a reasonable basis to believe the information can be used to identify the individual
3. Covered Entities
 - a. Health plans, health care clearinghouses, and healthcare providers who transmit any health information in electronic form in connection with a transaction
4. Business Associates
 - a. An entity that receives, creates, maintains, or transmits PHI for a function or activity regulated by HIPAA
 - b. For example, claims processing, data analysis, software vendors that have access to PHI
5. Treatment, Payment & Healthcare Operations (“TPO”) Exception
 - a. Covered entities can use PHI without a patient’s consent for treatment, payment and healthcare operations. That is, if AI is used for one of these purposes, the patient’s consent is not necessary



◆ WSJ NEWS EXCLUSIVE | TECH

Google's 'Project Nightingale' Gathers Personal Health Data on Millions of Americans

Search giant is amassing health records from Ascension facilities in 21 states; patients not yet informed

Other Data Privacy and Security Considerations

1. Not all health data is HIPAA data
2. HIPAA does not apply to most consumer-directed healthcare apps and devices
3. As an actor-centered rule, the HIPAA Privacy Rule does not afford protection to all healthcare data regardless of its source and use. Rather, only PHI collected, used, or maintained by Covered Entities is subject to the HIPAA Privacy Rule's requirements.
4. Without the Covered Entity nexus, this data remains unprotected. This is true regardless of the fact that this same data would be protected if provided to a Covered Entity.

Other Data Privacy and Security Considerations (cont.)

1. FTC Health Breach Notification Rule (“HBNR”)
 - a. HBNR helps fill the gap when HIPAA doesn’t apply.
 - b. HBNR applies to vendors of certain electronic “personal health records” containing “identifiable health information on an individual that can be drawn from multiple sources ... and managed primarily by the individual.” Essentially this is most health apps
2. Other Applicable Privacy Laws
 - a. 42 CFR Part 2 - Substance use disorder treatment programs
 - b. More stringent state law, including laws governing certain sensitive conditions and treatments, such as HIV status, mental health services and genetic information

For Your Information

FTC Finalizes Order with Flo Health, a Fertility-Tracking App that Shared Sensitive Health Data with Facebook, Google, and Others

June 22, 2021



For Release

FTC Enforcement Action to Bar GoodRx from Sharing Consumers' Sensitive Health Info for Advertising

Under proposed order, GoodRx will pay a \$1.5 million civil penalty for failing to report its unauthorized disclosure of consumer health data to Facebook, Google, and other companies

February 1, 2023



Other Legal Issues

Medical malpractice

- When is it necessary to specifically call out and explain the use of AI in diagnosis and treatment decisions?
- Should the patient be given the opportunity to refuse the use of AI in their diagnosis and treatment?
- Can a patient provide “informed” consent if it is a complex technology solution that providers themselves may not understand?
- Illinois
 - Physicians have a duty to inform patients of foreseeable risks, results, and alternatives that a reasonable physician would have disclosed in the same or similar circumstances
 - What would a “reasonable” doctor do under the same circumstances? A physician is not obligated to tell a patient every conceivable, **remote** risk of an operation, but they must tell the patient of a risk if a reasonable colleague would do so.

Liability

Medical malpractice

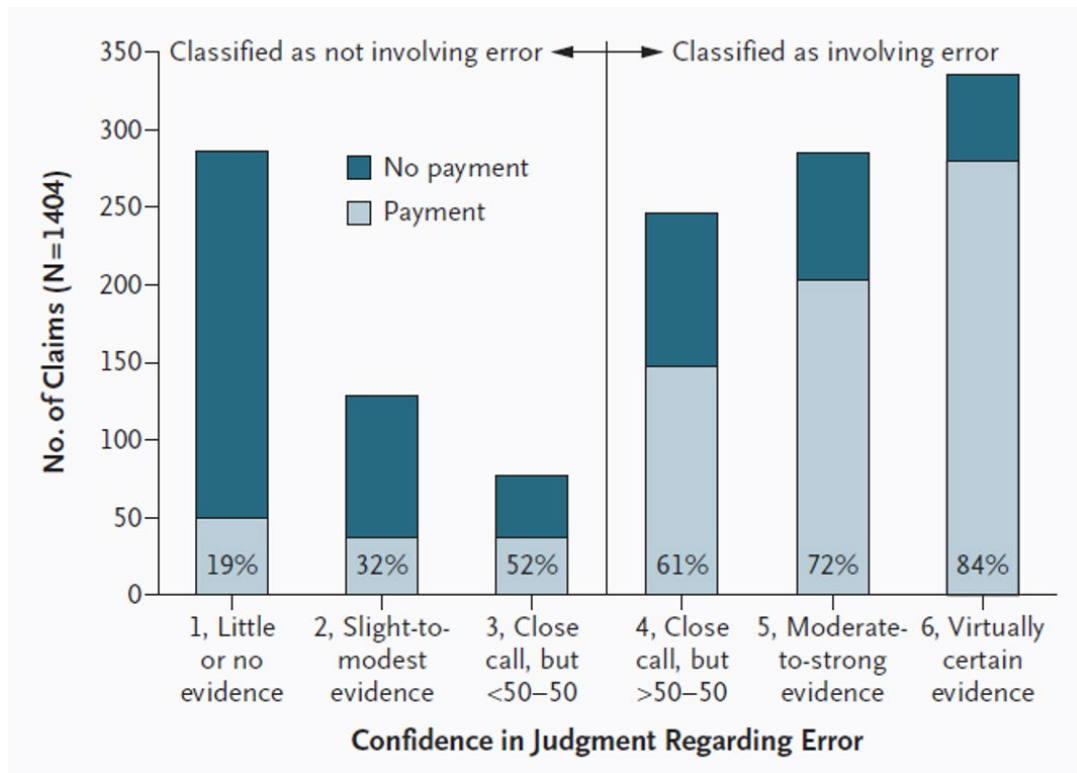
- AI is uncharted territory - no known case law to date
- Will AI elevate or otherwise change the standard of care?

Liability

Who might be liable?

- Individual providers (doctors, nurses, other medical professionals)
- Institutions
- AI developers

Claims, Errors, and Compensation Payments in Medical Malpractice Litigation



Liability

Malpractice (professional negligence)

- **Duty** - doctors and other medical professionals have a duty to treat patients consistent with the applicable standard of care
 - Physicians and medical professionals must use “the same degree of knowledge, skill and ability as an ordinarily careful professional would exercise under similar circumstances.”
 - Most states apply a national standard of care
- **Breach**
- **Causation**
- **Damages**

AI Treatment Recommendations

Price, Gerke, and Cohen hypothetical

“Assume a physician is treating a new patient with chronic migraines. The standard of care is Oldrug, a triptan with known moderate side effects. Another treatment, Newdrug, is approved for non-migraine use in cancer patients, but observational studies have shown that it may reduce migraines dramatically. However, Newdrug has potentially severe side effects and so is discouraged for use in treating migraines. The physician will prescribe one drug or the other. The physician enters her patient’s information into the electronic health record, and an embedded AI system makes a recommendation for treatment.”

AI Recommends	Which is:	Physician:	Result:	Is Physician Liable?	#
Oldrug (standard of care)	Right choice for the patient	Follows advice	Healing	Not liable (no injury)	1
		Rejects advice	Injury	Liable	2
	Wrong choice for the patient	Follows advice	Injury	Not liable (standard of care)	3
		Rejects advice	Healing	Not liable (no injury)	4
Newdrug (not standard of care)	Right choice for the patient	Follows advice	Healing	Not liable (no injury)	5
		Rejects advice	Injury	Not liable (standard of care)*	6
	Wrong choice for the patient	Follows advice	Injury	Liable*	7
		Rejects advice	Healing	Not liable (no injury)	8

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		Rejects advice	Healing	Not liable (no injury)	8

AI Treatment Recommendations

Price, Gerke, and Cohen

- Under existing law, “malpractice liability concerns incentivize physicians to follow the standard of care they would have followed before, no matter what the AI suggests.”
- Leads to using AI as confirmatory advice only

Key AI Principles (from 36 Publications of Principles)

- Privacy
- Accountability
- Safety and Security
- Transparency and Explainability
- Fairness and Non-discrimination
- Human Control of technology
- Professional Responsibility
- Promotion of Human Values



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Business Blog

Using Artificial Intelligence and Algorithms

By: Andrew Smith, Director, FTC Bureau of Consumer Protection

April 8, 2020

FTC - Using Artificial Intelligence and Algorithms

- Be transparent.
 - Explain your decision to the consumer.
 - Ensure that your decisions are fair.
 - Ensure that your data and models are robust and empirically sound.
 - Hold yourself accountable for compliance, ethics, fairness, and nondiscrimination.

Additional Panelists



Alexandre Carvalho, MD
Fellow, Infectious Diseases



Catherine Gao, MD
Instructor, Pulmonary &
Critical Care



Mohammad Hosseini, PhD
Postdoctoral researcher,
Preventive Medicine

Outpatient Case Study (Hypothetical)

53 yo female patient with paralysis, neurogenic bladder requiring self-catheterizations, recurrent UTIs with MRSA has been denied by her insurance company an important antibiotic pill to treat her painful urinary infection. Notably, MRSA is an aggressive, hardy pathogen, and the only other option would be an IV medication based on bacterial culture results. This would represent unnecessary escalation of care.

The Infectious Diseases provider will appeal. His clinic is overburdened by many such insurance denials on a daily basis, and he wants to try this “ChatGPT thing” to help write appeal letters. In this scenario:

→ *What are the potential legal pitfalls that this outpatient provider can incur? What is the best risk mitigation strategy here?*

→ *What if insurance companies also move to employ ChatGPT to “fast-track” claims?*

FTC says online counseling service BetterHelp pushed people into handing over health information – and broke its privacy promises

By: Lesley Fair

March 3, 2023



Inpatient Case Study (Hypothetical)

Imagine you are a busy critical care physician triaging patients to admit to the ICU. You have received pages about four different patients in the last ten minutes since starting your shift. You are most worried about patient A, but patient B has a higher risk score based on a model in the electronic health record. While you are busy evaluating patient B, patient A deteriorates and goes into cardiac arrest.

- Patients/families consent for procedures such as central lines and bronchoscopy. Is there any consent needed for use of algorithms in patient care?
- The family of the patient who went into cardiac arrest would like to take legal action. Do the algorithm/company/developers have any legal responsibility in this case; can they be sued?
- What is the regulatory oversight for algorithms like these?



05-28-21

How a largely untested AI algorithm crept into hundreds of hospitals

During the pandemic, the electronic health record giant Epic quickly rolled out an algorithm to help doctors decide which patients needed the most immediate care. Doctors believe it will change how they practice.

Research Case Study (Hypothetical)

Mandy is a dietician interested in the relationship between sugar intake during pregnancy and preterm birth. She starts using a ChatGPT-based application that obtains patient's consent to participate in research and records their daily food intake. Once a month, the application sends patients' information with dietary recommendations (based on existing literature) to Mandy. Subsequently, Mandy reviews these recommendations and sends them to patients.

After providing suggestions to 100 pregnant woman and following up on their end of pregnancy, Mandy notices that **none** of the white American mothers (n=78) had a preterm birth, but all African American (n=14) and Hispanic mothers (n=8) had a preterm birth. Mothers who had a preterm birth do not know about this trend and when asked about the research results, are told that the PI has moved to another institution and all their research activities are thus halted. Mandy stops using the application in her new institution and decides against publishing her results as other projects are prioritized.

Two years later, an advocacy group finds out about mothers who were negatively affected and contacts Mandy and other dieticians who were among early users but did not publish results.

- Are there any legal grounds to sue Mandy? What precautionary measures could Mandy have adopted?
- If Mandy were to publish her results, could developers of the app file a lawsuit against her (e.g., defamation)?
- Under what circumstances would legal authorities be able to pressure Mandy or developers to share data?

DA

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Are there any legal grounds to sue Mandy? What precautionary measures could Mandy have adopted?

If Mandy were to publish her results, could developers of the app file a lawsuit against her (e.g., defamation)?

Under what circumstances would legal authorities be able to pressure Mandy or developers to share data?




I am not a lawyer, but I can provide some general information regarding your questions. For legal advice specific to your situation, please consult with a legal professional.

1. Legal grounds to sue Mandy:

The legal grounds to sue Mandy would depend on the specific jurisdiction and its laws. Potential grounds could include negligence, breach of fiduciary duty, or failure to obtain informed consent. However, it is important to note that whether or not these grounds are valid would depend on the specific facts of the case, the applicable laws, and the strength of the evidence.

2. Precautionary measures Mandy could have adopted:

- Obtaining informed consent from participants, making sure they understand the purpose, risks, and benefits of the research.
- Ensuring that the study design and implementation follow ethical guidelines and best practices.
- Monitoring and addressing any potential biases or disparities in the study population or outcomes.
- Communicating with participants about the results of the study and any potential implications for their health.
- Consulting with legal and ethical experts throughout the research process.

- 
3. If Mandy were to publish her results, could developers of the app file a lawsuit against her (e.g., defamation)?

In general, defamation occurs when someone makes a false statement that harms another person's reputation. If Mandy publishes her results accurately and truthfully, and without making false or misleading statements about the app or its developers, it is unlikely that a defamation claim would be successful. However, this depends on the specific jurisdiction and its defamation laws.

4. Under what circumstances would legal authorities be able to pressure Mandy or developers to share data?

Legal authorities may be able to pressure Mandy or the developers to share data under various circumstances, such as:

- A court order or subpoena related to a lawsuit or investigation.
- Regulatory requirements for research involving human subjects, such as those established by Institutional Review Boards (IRBs) or government agencies.
- Contractual obligations between Mandy and the developers or between the developers and other parties.

Again, please consult a legal professional for advice specific to your situation.



Thank You!

Questions?

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