

Al in Healthcare: Examining the Matrix of Risk & Opportunities

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The information provided in this presentation offers risk management strategies and resources, and the slide content is intended to be used only with the accompanying oral presentation.

Guidance and recommendations contained in this presentation are not intended to determine the standard of care but are provided as risk management advice only. The ultimate judgment regarding the propriety of any method of care must be made by the healthcare professional.

The information does not constitute a legal opinion, nor is it a substitute for legal advice. Legal inquiries about this topic should be directed to an attorney.



Faculty

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What Is Artificial Intelligence (AI)?





Development of Al

1950s Artificial • First AI program developed in 1955 Intelligence Machine • 1980s • Machine learning begins to flourish • Requires human intervention Learning • Al boom driven by breakthroughs in Deep deep learning • 2010s Learning • Does not require human intervention



Datasets





Datasets in Healthcare



Genetic data

Wearable device data

Imaging data



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Impact of AI on Healthcare

Diagnoses

- Treatment
- Staffing Issues
- Research and Development
- Patient Experience



Size of Al Healthcare Market

- \$11B (2021)
- \$187B (2030)



Higher Education – AI in Healthcare Degrees/Certificates



BLAVATNIK INSTITUTE BIOMEDICAL INFORMATICS UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN



The Grainger College of Engineering Bioengineering

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Current Implementation





AI Utilization - Addressing Common Conditions



Early Diabetic Retinopathy Diagnosis



AI Utilization - Addressing Common Conditions

Sepsis Diagnosis





AI Utilization - Addressing Common Conditions



Prediction of Unfavorable Outcomes During Intrapartum Period



AI – Enhancing Breast Cancer Detection

- Al-supported results were similar to standard double reads
- Conclusion AI considered safe

"I think of AI as more validation. It doesn't sleep. AI doesn't get tired. The AI doesn't get fatigued..."

> Dr. Laura Heacock, a breast radiologist at NYU Langone Perlmutter Cancer Center





Potential Liabilities & Regulatory Framework





Current Regulatory Framework

AI Regulation

- 2019 Executive Order 13859
- 2020 Al in Government Act of 2020
 & Executive Order 13960
- 2023 FDA Guidance for AI/ML-Based SaMD
- 2023 Executive Order

AI Healthcare Regulation

- Federal/State
- American Medical Association efforts



Theories of Legal Liability



Professional Negligence

Product Liability

Breach of Contract

Fraud

Invasion of Privacy



Professional Negligence

Two Scenarios Leading to a Potential Claim Al prompt is correct and a physician overrides/ignores it

Al prompt is wrong and physician follows it "...[t]he ultimate responsibility for a diagnostic or therapeutic decision will likely remain with the physician, who has to validate the results of the CDS [clinical decision support] tool."

Hedderich, D.M., Weisstanner, C., Van Cauter, S. *et al.* Artificial intelligence tools in clinical neuroradiology: essential medico-legal aspects. *Neuroradiology* **65**, 1091–1099 (2023). https://doi.org/10.1007/s00234-023-03152-7



AI & Standard of Care





Biased Data in Healthcare AI – 2019 Landmark Study



- Hospital AI algorithm used to predict high-risk care management needs.
- Past cost data was used to determine risk.
- Unequal access to care for Black patients resulted in less money spent on their care.
- The need for healthcare ≠ prior healthcare costs.
- The AI discriminated against Black patients by assigning lower risk scores.



Obstacles to Eliminating Bias

We have work to do:

- Easy to miss embedded biases, even when you're looking for them
- Racial biases in AI will perpetuate

Researchers warn:

"Al-driven tools have the potential to codify bias in healthcare settings"

ACA Section 1557

 Covered entities must not discriminate on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making



Litigation Involving AI

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Health Insurance Claims Reviews

Allegation: Class action case alleging a national health insurance company's use of AI to review medical necessity of submitted claims violated mandatory rules and improperly denied claims.

Plaintiffs allege that, per California insurance law, "medically necessary" reviews of claims must be thorough, fair, and objective.

Plaintiffs allege the law requires that individual physicians review each claim separately to approve or deny claims.

Plaintiffs allege the insurer's use of the Al's algorithm to look for discrepancies unfairly denies claims without genuine investigation, as the physicians simply sign off on the denials.

Case is pending.

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HIPAA & AI

Allegation: Google and the University of Chicago Medical Center disclosed PHI when they supplied medical records to Al system.

As part of a research collaboration between the University of Chicago Medical Center and Google, the University gave Google anonymized patient medical records to implement Al-driven predictive health models.

Former patient sued Google and the University, alleging violation of HIPAA, among other causes of action.

The district court dismissed the case.

The Seventh Circuit affirmed the dismissal.

Dinerstein v. Google, LLC, 73 F.4th 502 (7th Cir. 2023)



What is on the Legal Horizon?

- Predictive models will be scrutinized
- Privacy claims will be common
- Plaintiffs will be creative





Risk Reduction

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Risk Reduction Strategies

Maintain Knowledge of Your AI Products/Services





Risk Reduction Strategies - Informed Consent

AMA Journal of Ethics





Risk Reduction Strategies - AI & Informed Consent





Follow the Standard of Care (SOC)





Looking Forward...

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AI – Confidence or Doubt?



- 60% of American adults were uncomfortable with reliance on AI
- 33% of American adults thought Al would lead to worse health outcomes
- 75% were worried their healthcare providers would adopt AI too quickly, without full contemplation of risks



Final Thoughts





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