

AI in Healthcare: Examining the Matrix of Risk & Opportunities

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January 30, 2024



1

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3

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Learning Objectives:

This enduring educational activity will support your ability to:

- Understand current and future uses of AI in healthcare.
- Identify patient safety issues and liability risks associated with incorporating AI into healthcare.
- Implement strategies to decrease liability risk and improve patient safety when utilizing AI in your practice.



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Poll Questions

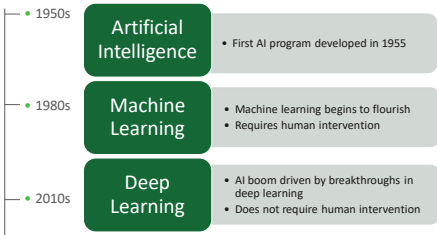
- On a scale of **1 to 10**, how would you rate your current proficiency with artificial intelligence (AI) in healthcare, generally?
- On a scale of **1 to 10**, how would you rate your current proficiency with artificial intelligence (AI) in healthcare, specific to potential safety and liability risks?
- Scale: **1** – lowest level of competency
10 – highest level of competency

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Development of AI



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AI in the Real World



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AI in the Real World



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**"Data! Data! Data! I can't
make bricks without clay."**
- Arthur Conan Doyle



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Datasets

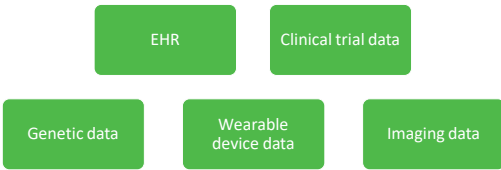


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Datasets in Healthcare



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AI Might Be Pandemic Boosted, But Not Pandemic Incepted



- AI in healthcare not a novel idea
- Finance sectors have long discussed the economic savings and overall investment of bringing AI to patient care settings
- As of 2017, the healthcare AI market was predicted to grow 10x by 2022
- AI's forecasted impact on unmet clinical demand has been a longtime focus

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Impact of AI on Healthcare

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



Size of AI Healthcare Market

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

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Higher Education – AI in Healthcare Degrees/Certificates



BLAVATNIK INSTITUTE
BIOMEDICAL INFORMATICS

UNIVERSITY OF ILLINOIS URBANA-CHAMPAIGN



Carnegie Mellon University
School of Computer Science

UF College of Public Health & Health Professions
UNIVERSITY OF FLORIDA



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Current Implementation



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AI Utilization - Addressing Common Conditions



Early Diabetic Retinopathy Diagnosis

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AI Utilization - Addressing Common Conditions

Sepsis Diagnosis



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AI Utilization - Addressing Common Conditions



Prediction of Unfavorable Outcomes During Intrapartum Period

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AI – Enhancing Breast Detection

- AI-supported results 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



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Identifying Patients at Risk of Stroke/Cognitive Decline



2022 Mayo Clinic Study Using AI-enabled ECG



AI-enabled ECGs PREDICT A-fib Associated With "Worse Baseline Cognition And Gradual Global Cognition And Attention Decline."



High A-fib Likelihood "Correlated With MRI Cerebral Infarcts."



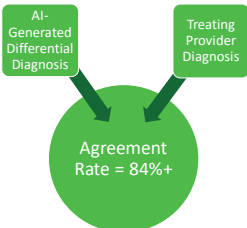
Further Studies Needed To Confirm If Medically Prudent To Start Preventative Treatment For Future Strokes In Identified Patients

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Diagnostic Support for Virtual Primary Care Visits



- AI-supported diagnoses showed significant overlap with treating provider diagnoses in this setting
- Highest agreement rates: (97.3 - 98.9%)
 - Bladder infection
 - Conjunctivitis
 - URI
- Lowest agreement rates: (20.8 - 42.4%)
 - Dermatitis
 - Acute bronchitis
 - Asthma
 - Unspecified abdominal pain

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Hospital Time and Resource Saving Devices



Improving Current Processes



Patient Triage – algorithms to assess patient demographics, symptoms, vital signs = prioritized care



Hospital Administration – predicts use of supplies, lengths of stay, duration in OR, staffing levels

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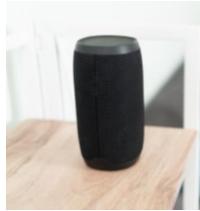


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Hospital Time and Resource Saving Devices



Voice Assistance in Patient Rooms



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Quality Improvement

- Data studied → Adverse events affected 1/4 of hospitalized patients
- AI used to combat preventable adverse events

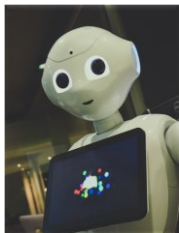


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Patient Experience - Pepper the Robot



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Potential Liabilities & Regulatory Framework



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Current Regulatory Framework



"Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan"

AI Regulation

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

AI Healthcare Regulation

- Nothing...yet
- American Medical Association efforts

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Theories of Legal Liability



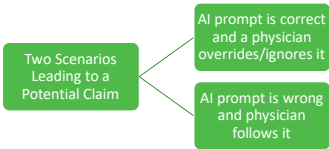
- Professional Negligence
- Product Liability
- Breach of Contract
- Fraud
- Invasion of Privacy

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Professional Negligence



“...[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.”

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Biased Data in Healthcare AI – 2019 Landmark Study



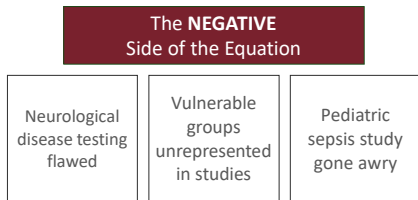
- Hospital AI algorithm used to predict high-risk care management needs.
- Past cost data was used to determine risk.
- Unequal access to care for Black patients resulted in less money spent on their care.
- The need for healthcare ≠ prior healthcare costs.
- The AI discriminated against Black patients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

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Examples of Bias in AI Algorithms...

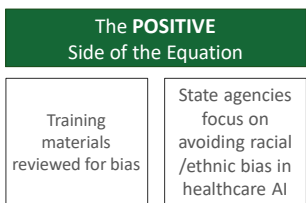


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...And Progression Away from Bias in AI Algorithms



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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

On the horizon – Proposed Rules:

- HHS (2022): 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
- HHS (2023): Requirement that developers engage in and make publicly known their practices to manage risk of bias, with ability for user review

Researchers warn:

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

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Recent AI Cases

- Privacy
 - *P.M. v. OpenAI LP*, Case No. 3:23-cv-3199 (N.D. Cal. 2023)
- Copyright
 - *Andersen v. Stability AI Ltd.*, Case No. 3:23-cv-00201 (N.D. Cal. 2023)
- Tort
 - *Walters v. OpenAI*, Case No. 23-cv-03122 (N.D. Ga. 2023)



38

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 AI's algorithm to look for discrepancies unfairly denies claims without genuine investigation, as the physicians simply sign off on the denials.

Case is pending.

39

HIPAA & AI

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

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What is on the Legal Horizon?

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



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Risk Reduction



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Risk Reduction Strategies

Maintain Knowledge of Your AI Products/Services




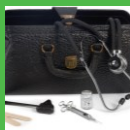
1 Avoid Wearing Blinders	2 Train Staff	3 Ensure Data Quality	4 Stay Informed/ Proactive	5 Lean into AI's Benefits
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Follow the Standard of Care (SOC)

 Use AI for its Intended Use	 Keep Up with Any Changes in SOC	 Train Staff on the Application of AI	 Use AI as a Resource in the Toolbox
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Risk Reduction Strategies - Informed Consent

AMA Journal of Ethics

Explain device use – how AI predicts or makes recommendations	Distinguish the roles played by AI v. the physician
Remain educated on construction of AI	
Educate on risks and unique benefits of AI	Share studies on the AI intended to be used, or AI in general

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Riding the Wave of AI

- Innovative AI will impact healthcare daily, and it may be difficult to stay on top of results of piloted AI algorithms.
- As this data rapidly changes, so does the regulatory landscape. There will be new vendors and products on the scene, and the number of hospitals, universities, and practices using AI will only increase.
- It is wise to task a person or team, designated to stay on top of AI trends in healthcare.



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Looking Forward...



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AI's Impact on the Human Factor

- National Nurses United Study
 - 1,042 RNs surveyed
 - Nurses vs. AI
 - Ethical considerations
- Columbia University Study
 - Quantifying Nursing Intuition



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AI – Confidence or Doubt?



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

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Final Thoughts

- Healthcare Takes Humans to Do the Job
- You Remain Integral to Your Patients
- AI is Not Ready to Take the Reins...
- ...But Learn About and Seek Out the Best AI for You



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Poll Questions

- On a scale of **1 to 10**, how would you rate your current proficiency with artificial intelligence (AI) in healthcare, generally?
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