Understanding Liability Risk from Using Healthcare AI Tools

Michelle Mello, JD, PhD

Stanford | Health Policy
Freeman Spogli Institute and Stanford School of Medicine

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Roadmap

1. The AI adoption landscape
2. AI-related liability risk and why it matters
3. Recommendations for managing risk

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Key healthcare AI modalities, simplified

Predictive AI

Uses machine learning techniques and massive patient data troves to train an algorithm to classify or predict things

- *Will this patient need a blood transfusion during surgery?*
- *Does this EKG suggest hypertrophic cardiomyopathy?*
- *Can daily lab tests be safely discontinued for this patient?*

Generative AI

Uses a large language model to create novel text in response to a prompt

- *What was discussed and decided during this office visit?*
- *What are the radiologist's impressions from this x-ray?*
- *When did this patient last report chest pain?*

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Types of healthcare AI tools

Clinical decision support

Healthcare operations

Direct-to-consumer

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Generative AI use cases

USE CASE	OPPORTUNITY			ADOPTION STAGE					
	Pain point intensity	Current level of manual work	Opportunity Score	Not yet started	Ideation	POC	Active pilot	Full rollout	Adoption Score
Patient triage	36%	63%	49	34%	17%	25%	19%	5%	29
Provider credentialing and enrollment	33%	51%	42	39%	19%	19%	14%	9%	27
Patient scheduling	37%	42%	39	19%	21%	26%	28%	5%	36
Staff scheduling	36%	42%	39	26%	19%	25%	19%	11%	34
Risk adjustment	42%	46%	44	16%	30%	24%	24%	6%	35
Care gap identification	37%	53%	45	24%	13%	26%	32%	5%	36
Clinical trial coordination	26%	58%	42	21%	21%	37%	11%	11%	34
Documentation support (scribes)	55%	31%	43	3%	11%	27%	38%	22%	53
Follow-up care	41%	51%	46	19%	31%	20%	22%	8%	34
Referral management	34%	51%	42	25%	19%	36%	13%	8%	32
Quality metrics and patient registry	47%	32%	40	23%	28%	21%	25%	4%	32

Note: Opportunity Score is calculated as the average of pain point intensity (% respondents claiming a job is a significant pain point) and current level of automation (% respondents of describing job as mostly manual process); Adoption Score calculated using weighted average of development stage where net yet started is 0% adoption and implementation/full rollout is 80% adoption | Source: Bain GenAI Survey (N = 408)

Clinical summarization tools at the leading edge

Patient email drafters also popular

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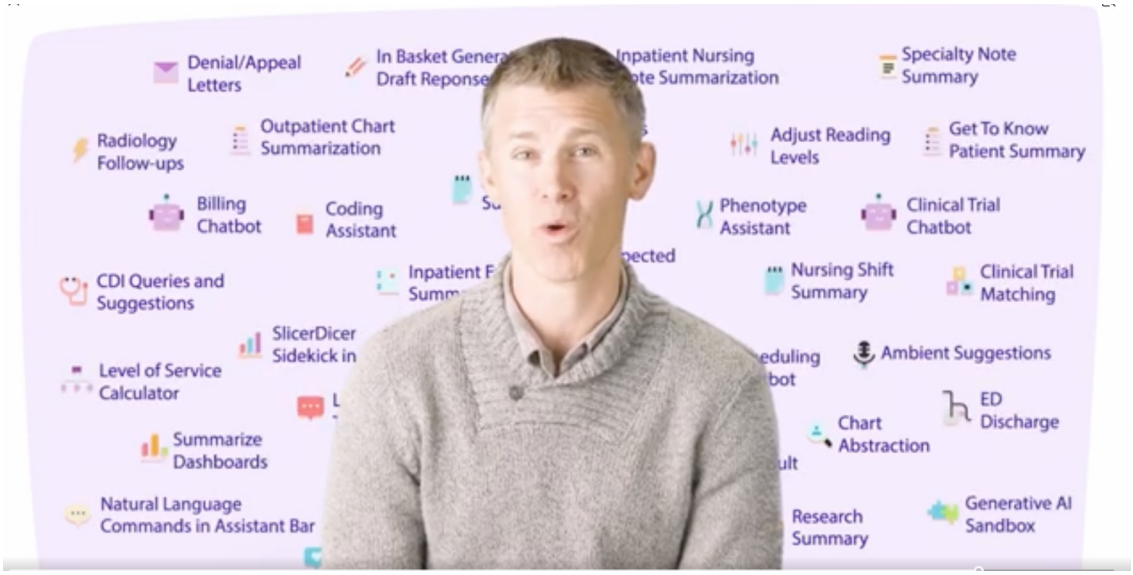
Epic's builds



6 Source: https://www.epic.com/epic/post/cool-stuff-now-epic-and-generative-ai/

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Lawyers' warnings

"can be a disaster for health care providers"

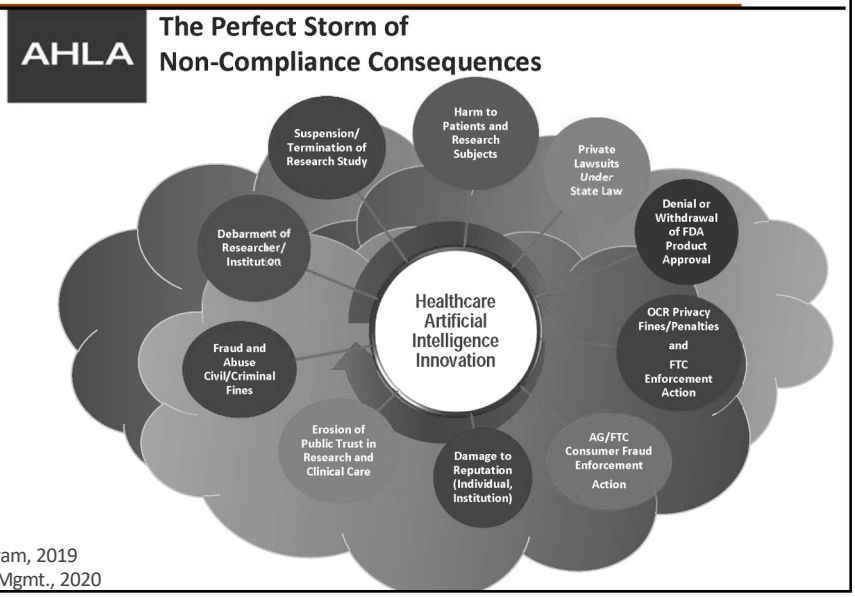

Image: Broccolo BM, AHLA In-House Counsel Program, 2019
Quotation: Keris MP, Am. Soc. for Healthcare Risk Mgmt., 2020

Reasons for worry

- Less testing than some other clinical innovations
- When an area is under-regulated, liability tends to fill the gap
- Errors may propagate over many patients
- Public distrusts AI
- Harm events likely to draw public attention
- Judges are inexperienced, doctrine is underdeveloped
- Unclear who will be left holding the ball

Reasons for reassurance

- Few negligent injuries become claims
- Scant evidence of software-related claims to date
- Significant hurdles for plaintiffs in AI cases

Challenges for plaintiffs in AI cases

What Plaintiff (P) Must Prove	Challenges
D owed P a duty	If AI is in certain FDA-reviewed medical devices, product liability claims may be *preempted*
D's conduct fell below the standard of care	• Model opacity makes it hard to prove physician's decision to accept/reject output was unreasonable • Wrong model output for a particular patient may not have been foreseeable by physician • AI may not be considered a "product" • Hard to show there's a reasonable alternative safer design
D's conduct caused P's injury	Model opacity makes it hard to prove that wrong output occurred because of a *defect*

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Software torts to date

- 51 cases involving personal injury (not all in health care)

Type of fact pattern	Examples
Patient sues developer when software used to manage care fails & hospital for negligently maintaining it	• Defective user interface in drug-management software leads physicians to wrongly believe they have scheduled meds • Hospital fails to update software on surgical microscope
Patient sues physician for relying on software recommendations & developer for software design	• Cardiac health screening algorithm classifies a young adult patient as low risk despite family history of congenital heart defect.
Plaintiff sues everyone when device-based software fails	• Reprogramming of infusion pump causes lethal morphine dosing

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Key takeaways from these cases

- AI's complexity worsens information deficits that make it hard for plaintiffs to identify design defects in software.
- AI's varying performance across groups raises questions about when physicians should've known output wasn't reliable for a given patient.
- Courts don't distinguish between AI and other software.

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AI risk assessment

Likelihood & Nature of Error

- Wrong model output
- Clinician nonadherence to correct output
- Poor integration into clinical workflow

Redress Potential

- Whether claim is preempted
- Severity of harm
- Patient characteristics affecting case's attractiveness to plaintiff's attorneys
- Ease of proving negligence & causation
- Division of causal responsibility among developer, clinicians, hospital, & patient

Catch Opportunity
(by Clinician, Patient, or Another System)

- Extent of coupling
- Time sensitivity
- Situational opportunity

Harm Potential

- Severity of health condition involved
- Clinical importance of the tool's function

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Risk management recommendations

- Calibrate adoption & oversight decisions to risk level
- Take advantage of the buyer's market. Bargain for:
  - Information & other supports for monitoring
  - Indemnification
  - Adequate insurance for developer
  - Non-applicability of disclaimers in Terms of Use

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OpenAI

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Terms of Use

- You must not use any Output relating to a person for any purpose that could have a legal or material impact on that person, such as making credit, educational, employment, housing, insurance, legal, medical, or other important decisions about them.

Risk management recommendations

- Anticipate evidentiary issues in litigation
  - Document inputs, outputs, versions, & reasons for accepting/rejecting recommendations
- Acknowledge and help users resist automation bias

The legal standard of care for malpractice

The custom standard:

The care that a reasonable practitioner in the defendant's specialty would provide in similar circumstances.

The current standard:

The care, skill, and knowledge regarded as competent among similar medical providers in the same or similar circumstances.

Customary practice may fall short of what medical professionals regard as competent. "It should be no defense that many other providers render similarly deficient care."

- Restatement (Third) of Torts: Medical Malpractice § 5(a) (2024)

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Risk management recommendations

- Insist that developer provide key information about a tool's performance and training
- Set an institutional policy about patient notification for each tool

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Should patients be told about uses of AI?

Arguments against:	Arguments for:
Use of other decision supports usually isn't disclosed	AI is different; it's "material information" to patients
Patients care about physicians' judgments, not how they make them	Like other evidence, helps patients weigh treatment recommendations
Patients have low understanding of AI	Clinician can help patients understand
Might create distrust	Candor engenders trust; use of AI will come to light in litigation

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Ask, tell, or neither?

How great is the risk of physical harm?

- Risk posed by tool
- Likelihood that errors will reach patients
- Severity of potential harm

Does patient have a meaningful opportunity to exercise agency?

- Opt out
- Alter behavior in ways that promote their interests

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Source: Mello, Char & Xu, *JAMA* 2025

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What should be disclosed?

1. The fact that an AI tool is being used
2. What functions it performs
3. Basics of how it works, including clinician's role
4. Why the organization believes it improves care
5. Basics of how the organization monitors performance, including in subgroups
6. Where applicable, patient's choices about having the tool used

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Sample consent for an ambient scribe

Illinois requires 2-party consent for recording private conversations

Source: Mello, Char & Xu, *JAMA* 2025

Modality

Information is distributed via paper information sheet when patient checks in for clinic visit; nurse elicits oral consent when patients are brought to examination room.

Information Sheet

Apex Hospital uses an artificial tool (AI) tool called Intelligent Ear to help your physician take notes on your visit today and summarize them in your medical record. Under California law, you have the right not to have this tool used.

Intelligent Ear makes an audio recording of your physician visit and uses AI to write out the conversation in full. It then uses a different kind of AI to generate a summary of the important parts of the conversation. Your physician will have the opportunity to review and edit this summary before making it part of your medical record.

The audio recording is securely sent to the company that developed Intelligent Ear, but the company does not keep any information about you once the visit summary is created.

Apex Hospital is using this tool because of evidence that it can improve care. Having this type of aid enables physicians to keep their focus on you during your visit and save time writing notes at the end of the day. Testing showed Intelligent Ear generates good-quality summaries and that physicians find it helpful.

The tool performs somewhat less well for people with accented English, people with speech impediments, and conversations with more than 2 speakers. To help avoid inaccuracies, your physician has been trained to review summaries with special care in those circumstances. Apex Hospital is using this tool after studying the results of a pilot test at Apex, and continues to monitor the tool's performance to make sure it is working well for all types of patients.

We are excited to be able to offer this tool in our continuing efforts to deliver the best care possible. If you do not wish to have the tool used in your visit today, please let your nurse know.

Nurse Script

Did you have any questions about the scribe tool that the physician uses? Is it OK with you if the physician uses it today?

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Risk management recommendations

- Insist that developer provide key information about a tool's performance and training
- Set an institutional policy about patient notification for each tool
- Establish an institutional governance process

Key elements of a governance process

- Assessors have data science, clinical QI, and ethics expertise
- Assessment centers on a *workflow*, not a tool
- Decision-makers have the leverage to require review
- Decision-makers are willing to say no
- Clear communication to departments about *what*, *why*, *how*, and *how long*
- Assessors use a collaborative / coaching approach

Making the decision

Assessment elements:

1. Achievable utility, including variations by subgroup
2. Financial sustainability
3. Ethical considerations

Executive Committee also considers:

- Institutional priority?
- Monitoring plan feasible?
- Legal considerations?

27 Source: Callahan A et al., *NEJM Catalyst* 2024;5(10).

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More information

Deep dive into AI liability & risk management

Informed consent recommendations

Liability issues from using ChatGPT

Vetting AI tools for ethical problems

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