# Artificial intelligence in healthcare

## Risks and benefits for medical professional liability

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60 MINUTES
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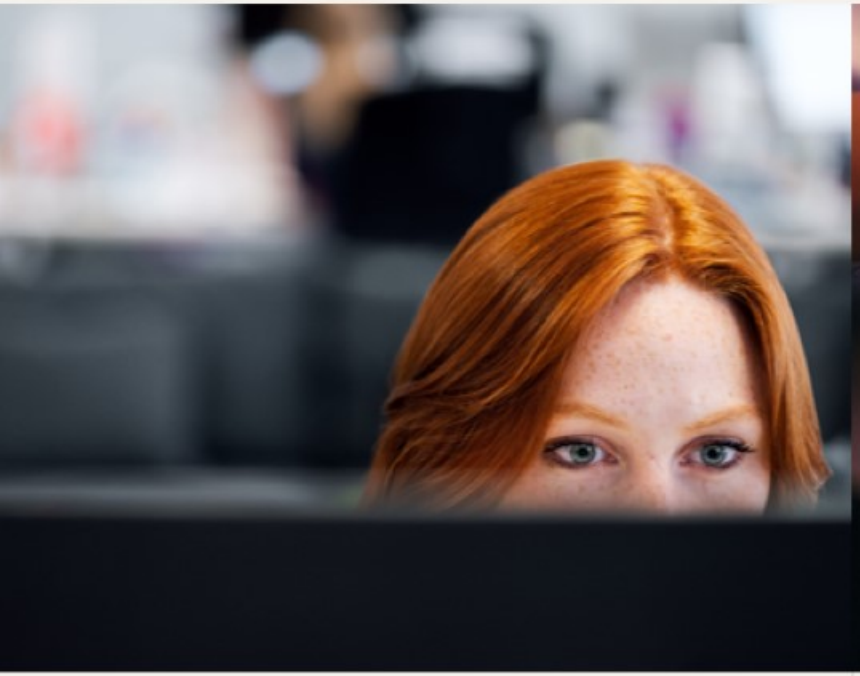
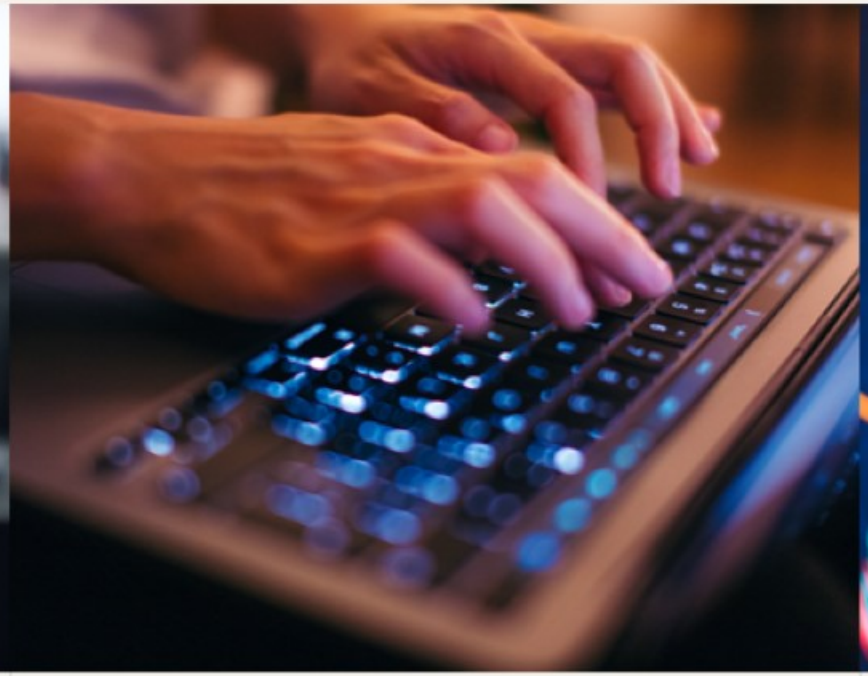
Aaron Weisz
"The Godfather of AI"
0:01 / 13:11 • Intro

# Artificial intelligence (AI) definitions





**Artificial intelligence**

"AI leverages computers and machines to mimic the problem solving and decision-making capabilities of the human mind." (1)

**Artificial intelligence**

The "science and engineering of making intelligent machines, especially intelligent computer programs." (2)

**Machine learning**

"M.L. is a branch of AI and computer science which focuses on the use of data and algorithms to imitate the way humans learn, gradually improving its accuracy." (3)

(1) https://www.ibm.com/topics/artificial-intelligence
(2) US FDA Artificial Intelligence/Machine Learning (AI/ML) – Based software as a medical device (SaMD) action plan. January 2021. https://www.fda.gov/media/145022/download.
(3) https://www.ibm.com/topics/machine-learning

# AI growth

AI will transform healthcare delivery over the next decade.

The amount of money being invested in AI by tech companies and healthcare organizations has grown and will grow exponentially.

$15.4 billion in 2022 and will grow annually by 37.5% from 2023 to 2030. (4)

(4) Mills, Terence. Member, Forbes Technology Council. The Risks and Benefits of A.I. in Medicine. March 23, 2021. https://www.forbes.com/site/forbescouncil2021/03/23.

# AI potential benefits

# AI potential benefits

- Bring to bear all medical knowledge at point of care: Benefit to clinical care
- Strengthen and speed up clinical research and drug development
- Improve care processes that create inefficiencies and patient injuries
  - Medication errors

# AI potential benefits

- AI can predict patient health trajectories
- Recommend treatments including surgery
- Monitor patients (inpatient, home settings, LTC)
- Automate labor-intensive tasks
- Record digital notes

# AI potential benefits

AI will improve radiology reads

AI will improve interpretation of pathology studies/tissue

AI will help deliver better therapies

Precision medicine: Based on patient genetics, age, conditions and environment

Customized treatment plans

# AI potential benefits

- Shorten provider time spent on the EMR
  - More patients can be seen daily
  - More complete and accurate EMR entries potentially
  - Avoid physician burnout
- Manage repetitive tasks
- Apply therapies and tests more rapidly
  - Faster scan times
- Use predictive analytics to improve patient care
  - Before patients deteriorate
  - Examples: Pneumonia, renal injuries/failure

# AI potential benefits

## Example: Radiology

- ML system is given a large number of chest x-rays and asked which of them indicate a lung tumor is present
- Radiologist initially determines if the review is accurate
- The ML system will gradually, with enough reviews, become as proficient as the best radiologists and eventually exceed their capabilities
- It will find tumors that even the very brightest radiologists missed
- Stanford researchers created an algorithm to detect pneumonia from a chest x-ray
- This functions at a level exceeding current practicing radiologists

*Sources:*
*Marchant, Gary E and Tournes, Lucille M. AI Healthcare Liability: From Research Trials to Court Trials. J. Health & Life Sci, Feb 2019 at 23.*

# AI: Potential benefits

Example: Ophthalmology

- ARDA: Automated Retinal Disease Assessment
- Accurate interpretation of retinal scans to detect diabetic retinopathy
- Can provide greater access to eye care in third-world countries
- Expansion in use to other eye diseases
- Detection of diabetic retinopathy was at a level equal to or exceeding opthalmologists

# AI potential benefits

**LVO stroke platform (large vessel occlusion)**

Analyzes CT scan images to detect potential strokes by sending automated alerts (still limited use)

**AI – enabled stethoscope**

Uses AI to detect specific heart sounds and detect cardiac abnormalities

**Caption guidance**

Software to assess the diagnostic quality of echocardiograms which are viable

# AI potential benefits

- Pushing beyond the capabilities and clinical skills of human providers
  - Algorithms keep getting better and better
    - Example: Predicting the onset of acute kidney injury up to 48 hours before occurrence
    - Today, injury often is not noticed until after it happens
  - Broadening medical knowledge to reduce the time of scarce physician specialists
    - Ophthalmology, other specialties

# AI potential benefits

| | |
|---|---|
| Staffing → | – Predict which departments may need additional staffing/resources |
| Resource allocation → | – Suggest which patients are likely to benefit most from scarce medical resources (organs?) |

# AI potential benefits: Diagnostic error

Clinical Risk →

## CLINICAL RISK

- Diagnostic error causes as many as one third of all malpractice claims per a 2019 study.

Clinical Benefit →

## CLINICAL BENEFIT

- AI can help avoid and prevent diagnostic error reducing injuries and claim.

Newman, Toker, David E MD et al. Serious misdiagnosis related harms in malpractice claims: The "Big Three" – vascular events, infections and cancers. Diagnosis 2019: 6 (3): 227-230

# Potential risks

# AI potential risks

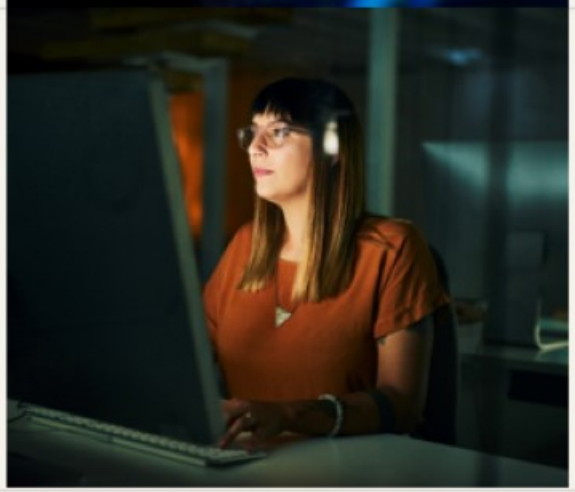
- Obtaining high quality data in designing AI tools can be difficult
- Recognizing limitations and bias in data
- Keeping clinical decision support algorithms current with good data
- Poorly designed systems/algorithms can harm patients: Inaccuracy
- ML system malfunctions can harm patients
  - Incorrect radiology or pathology reads
- Incorrect diagnoses due to insufficient information
  - On the patient
  - In the algorithm
- AI can suggest a therapy but fail to consider side effects

# AI potential risks

Safe use requires trained clinician-users who can ID and report emerging problems

"A major driver of AI system malfunction is…data set shift"

A ML system underperforming due to a mismatch between the data set as deployed and the data on which it is applied



Excellent examples in NEJM, July 15, 2021, correspondence

# AI potential risks

- AI can suggest a therapy but fail to consider side effects, unintended consequences
- As AI is increasingly used, there can be potential liability for failing to use it
- AI use can create complex claims
  - MPL, GL, tech E&O, products liability, cyber, life sciences coverages

# AI potential risks

**Who is potentially liable for patient injuries?**

- The treating physician using AI
- Any other clinical staff or tech staff administering or interpreting AI tools
- The manufacturer
- The facility/system where the patient received care
- Multiple insurance coverages could apply
  - MPL
  - Products liability
  - Tech E&O
  - Cyber
  - Life sciences
- Products liability laws are generally more favorable to plaintiffs – strict liability
- Manufacturers may have deep pockets
- If AI systems become better than humans at diagnosis treatments or other tasks, is it malpractice for a human to do the same?
- Improperly designed/applied AI tools can harm large groups of patients - batch claims

# AI potential risks

| **How can the use of AI be validated before use?** |
| --- |
| No agreement on this issue |
| Controlled studies? How many? |
| The benefits could be so great as observed in initial studies, more immediate use may be justified |
| Very little legal precedent on how rapid technological advancements will be dealt with in litigation by courts |

# AI potential risks

**The legal system**

- Should manufacturers, physician/nurse users, hospitals, other healthcare entities using AI have limited liability for patient injuries in order to promote development and advancement of AI tools?
  - Federal/state legislation
  - Hospital associations: lobbying
- How do we promote innovation in patient care yet fairly compensate injured patients?
- AI MPL litigation (and/or products liability, life sciences, tech E&O litigation) could discourage the development of AI clinical tools
- Hospital systems could have vicarious liability exposure for improper use of AI/unsafe development/application of the AI tool
- Are AI software/devices subject to traditional products liability law?
  - Poor design
  - Failure to warn about risks
  - Manufacturing defects
- Do hospitals (ACMCs?) have products liability exposure for significant AI tool modifications?

# AI potential risks

Algorithms may incorporate racial and ethnic biases

Chatbots = Google's Bard and ChatGPT were recently found to respond to medical questions with falsehoods about black patients

Privacy risks may be compromised with virtual care technology and any use of PHI

*Source: Burke, Gavance and O'Brien, Matt. Stuff: Chatbots Perpetuating racist medical ideas. Detroit Free Press. Ap News. October 22, 2023 at 16A*

# AI potential risks

- Defendants will need to collaborate on what will be complex claims
  - Will they?
  - Divergent interests
  - What is the manufacturer's role in litigation?
- No legal precedent on these new types of claims
- Documentation/archiving of algorithm changes

# AI potential risks

- When does AI become the standard of care?
  - Physician/provider judgement
- Can there be potential liability for failing to use it?
- How will juries perceive AI in healthcare setting/litigation?

# AI potential risks

| **Standard of care** | **What is the "tipping point" at which the AI/ML tool is the standard of care?** |
| --- | --- |
| – The rapid developments of AI/ML technology presents a huge challenge for users and the potential for mistakes<br>  – Keeping clinical guidelines/literature up to date<br>  – Lack of proper training<br>  – Failure to use the newest/best technology available | – Who decides?<br>– Medical literature<br>– Keeping institutional guidelines current |

# AI potential risks

**Standard of care**

- Malpractice law applies the “reasonable physician standard”
  - Expert testimony
- What happens when AI displaces the treating physician’s professional judgment?
- Should the AI tool be evaluated under the medical negligence standard or the products liability standard?

# AI potential risks

**The FDA: See the AI/ML Action Plan January 2021**

- The FDA's role is to oversee the patient safety and effectiveness of AI/ML devices
- The FDA has reviewed and authorized a continually growing number of devices (520 total as of 1/23)
- 30% increase from 2022-2023
- 87% were for use in radiology
- Key question: AI in health care is moving at warp speed – can the FDA keep up?

# AI potential risks

**FDA**

- AI's benefit is that it attains optional performance over time
- FDA ordinarily requires approval for hardware - based medical devices
  - Slow process

- New FDA draft guidance was issued in April 2023
  - "Predetermined Change Control Plan"
    - Allows manufacturers to predict algorithm changes and make future modifications without submitting to the agency, with limits
    - Still promotes safety and effectiveness of the devices

FDA in January 2021 released a document titled:

- Artificial Intelligence / Machine learning (AI/ML)
  - Based software as a medical device action plan
- Sets forth a multi-pronged approach to advance FDA oversight of AI/ML – based medical software.
- Documents with more specific guidance have been issued in recent years
- To date, the FDA treats AI software as medical devices
  - Products liability exposure vs. malpractice
- Other guidance document examples:
  - September 2022 – Clinical Decision Support Software
  - April 2022 – Cybersecurity in Medical Devices:
    - Quality system considerations and content of premarket submissions

Source: Boubker, Jess and Faget, Kyle. FDA's New Guidance proposes Flexible use of AI

# Managing the risks

# AI: Managing the risks

Create AI (risk management) task force

Use an enterprise risk management approach

Training providers in its use and limitations before deployment

Rigorous testing by clinicians prior to use

Use patient simulation labs?

# AI: Managing the risks

| | | |
|---|---|---|
| Understand and apply the regulatory framework (FDA). | Indemnification agreements with vendors. | Analyze various potential claims scenarios with defense counsel and brokers. |

# AI: Managing the risks

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AI implementation: ERM approach

Hospital-wide, system-wide training and implementation

Understand and apply the regulatory framework - FDA

# AI: Managing the risks

- Diligent risk management and inhouse legal staff oversight is needed
- Anticipate that plaintiff's lawyers will want an "audit trail" of:
  - Changes to AI – enabled software and devices
  - How AI impacted physician judgment and decisions

# Artificial intelligence in health care

AI will transform healthcare delivery and future malpractice claims

Be prepared

There will always be room for human judgment in clinical settings using AI

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