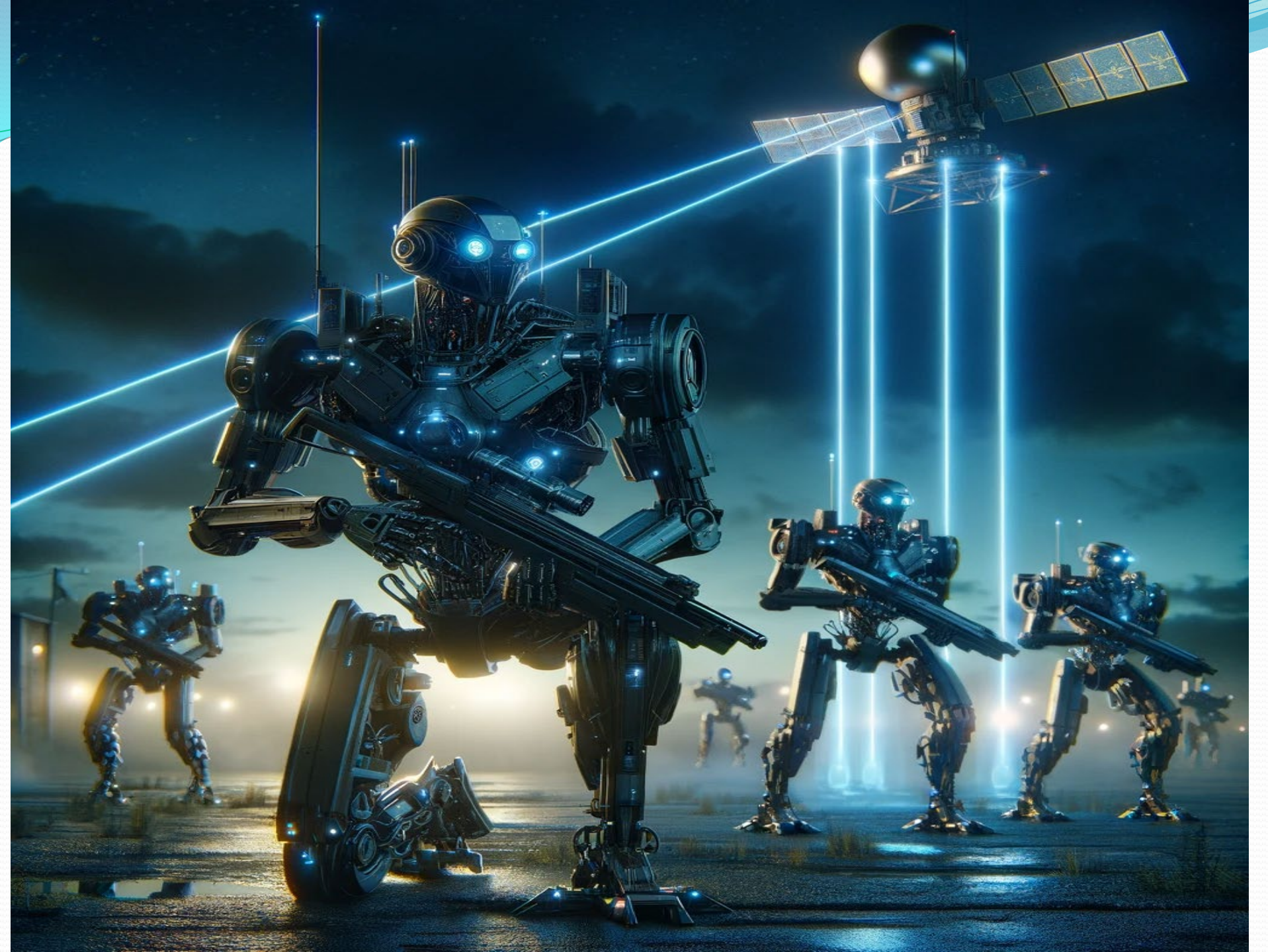


AI in Healthcare: Legal and Ethical Challenges

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Partner



FOSTER & ELDRIDGE LLP



Poll Time!

Are A.I. applications being used at your practice currently?

1 = Yes, I am aware of A.I. use at our practice.

2 = I am not sure about the status of A.I. use at our practice.

3 = No A.I. applications are currently being used at our practice.

What is AI?

“The capability of a device to perform functions that are normally associated with human intelligence such as reasoning, learning, and self-improvement.”

[Definitions are from ANSI INCITS 172-220 (R2007) Information Technology -- American National Standard Dictionary of Information Technology (ANSDIT), and cited in NIST's U.S. Leadership in AI: A Plan for Federal Engagement in Developing Technical Standards and Related Tools (August 9, 2019).]

Historic AI Use in Healthcare

- Radiology overreads (CAD)
- Clinical Decision Support
- Diagnostic Aids
- Simplistic Chatbots (marketing)
- Scheduling, Tracking, Following
- Dashboarding

Emerging AI Use in Healthcare

- Medical Imaging Analysis
- Predictive Analytics
- Drug Discovery/Development
- Health Monitoring and Wearables
- Virtual Health Assistants
- Clinical Decision Support Systems (CDSS) or Predictive Decision Support Interventions (DSI)
- AI Augmented Surgery

Emerging AI Use in Healthcare

Medical Imaging Analysis:

Utilizing AI algorithms for primary analysis of medical images such as X-rays, MRIs, and CT scans for faster and more accurate diagnosis.

Predictive Analytics:

Forecasting patient outcomes and identifying potential health risks based on large datasets, helping in proactive care management. Forecasting cardiac conditions, tailoring cancer treatments, etc.

Emerging AI Use in Healthcare

Drug Discovery and Development:

Accelerating drug discovery processes by analyzing vast amounts of biological data and predicting the efficacy of potential drug candidates.

Virtual Health Assistants:

AI-powered virtual assistants that provide patient education, medication reminders, and answer basic health-related queries.



Emerging AI Use in Healthcare

Clinical Decision Support Systems (CDSS) or Predictive Decision Support Interventions (DSI):

AI systems that assist healthcare providers in making clinical decisions by analyzing patient data and offering evidence-based recommendations.

Health Monitoring and Wearables:

AI-enabled wearable devices and mobile apps that monitor vital signs, track fitness, and provide early warnings for potential health issues.

Emerging AI Use in Healthcare


Natural Language Processing (NLP):

Analyzing and extracting information from unstructured medical data such as physician notes, clinical documents, and research papers.



Show me the patient's most recent health summary

Patient is a 56 y.o male with history of DM, HTN who presents with facial itching and lip swelling after dinner. Patient received 125mg solumedrol, famotidine and nenedryl in the ED. He was discharged home with an epi pen.



Ambient Scribing



Ambient Scribing

- In October 2023, The Permanente Medical Group (TPMG) enabled ambient AI technology for 10,000 physicians and staff.
- Initial reviews from clinicians were favorable.
- “Although a review of 35 AI-generated transcripts resulted in an average score of 48 of 50 in 10 key domains, AI scribes are not a replacement for clinicians. They can produce inconsistencies that require physicians’ review and editing to ensure that they remain aligned with the physician–patient relationship.”

Ambient Scribing

- Wiretap statutes anyone?
- Documenting consent.
- Picking up other people's voices.
- Impact on clinical relationship.
- Patient surveillance?
- Discovery

GenAI

- Machine Learning
- Predictive Language
- Generative AI

- The Data
- The Algorithm
- The Models

Basics

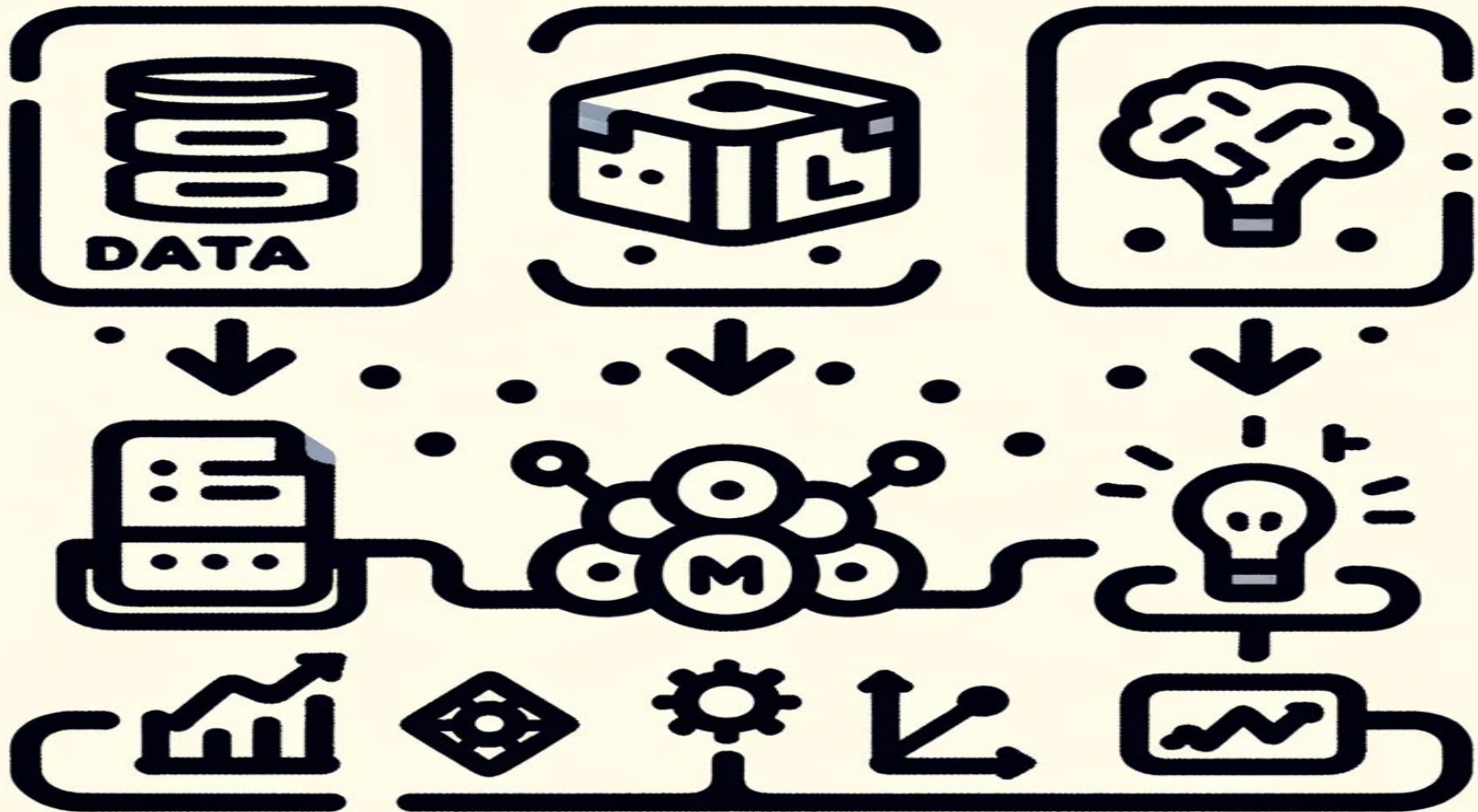
GenAI:

Review
Access Internet
Converse
Write
Code
Compose
Research
Analyze
Predict

Data

Algorithm/Model

Output



Predictive Language

“Do you want to build a _____?”

“Who you gonna call, _____?”

“I have a _____?”



Patient Use

ChatGPT



Examples

"Explain quantum computing in simple terms" →

"Got any creative ideas for a 10 year old's birthday?" →

"How do I make an HTTP request in Javascript?" →



Capabilities

Remembers what user said earlier in the conversation

Allows user to provide follow-up corrections

Trained to decline inappropriate requests



Limitations

May occasionally generate incorrect information

May occasionally produce harmful instructions or biased content

Limited knowledge of world and events after 2021



is risk management important to a healthcare organization



Yes, risk management is incredibly important to healthcare organizations. Healthcare organizations are responsible for providing safe and effective care to patients, and risk management is an essential component of achieving this goal.



Risk management in healthcare involves identifying potential risks to patient safety and taking steps to mitigate those risks. This can involve everything from implementing safety protocols and procedures, to training staff on best practices for patient care, to monitoring and analyzing data to identify areas where improvements can be made.

In addition to protecting patient safety, effective risk management can also help healthcare organizations avoid costly legal claims and regulatory penalties. By identifying and addressing potential risks before they become major problems, healthcare organizations can help protect their patients, their staff, and their bottom line.

CB at what age should i consider PSA testing



The decision to undergo prostate-specific antigen (PSA) testing should be based on individual factors such as age, family history, and overall health. Generally, it is recommended that men discuss the benefits and risks of PSA testing with their healthcare provider starting at age 50 for men of average risk.



However, men who are at higher risk for prostate cancer, such as those with a family history of the disease, African American men, or men with certain genetic mutations, may benefit from earlier or more frequent testing.

It's important to note that PSA testing is not without risks, and false-positive results can lead to unnecessary biopsies and treatments that can cause side effects such as urinary incontinence and erectile dysfunction. Therefore, the decision to undergo PSA testing should be made after careful consideration of the risks and benefits, and in consultation with a healthcare provider.

DOCTOR VS CHATGPT

DOCTORS RATED RESPONSES TO
200 PATIENT QUESTIONS

5%

EMPATHETIC
RESPONSES

45%

21%

HIGH QUALITY
RESPONSES

79%

21%

PREFERRED

79%

DATA SOURCE: UC SAN DIEGO | GRAPHIC: DAILYMAIL.COM



If a patient comes to the emergency department complaining of abdominal pain what should be done?



If a patient comes to the emergency department complaining of abdominal pain, the first step should be to assess the severity and location of the pain, as well as any other symptoms the patient may be experiencing. The patient should also be asked about their medical history and any medications they are currently taking. Based on this information, the healthcare provider may order diagnostic tests such as a CT scan or an ultrasound to determine the cause of the abdominal pain. Depending on the cause and severity of the pain, the patient may be treated with medications or may require surgery. It is important to promptly address abdominal pain as it can be a symptom of a serious medical condition.





what tests should be ordered for this patient



The tests that should be ordered for a patient complaining of abdominal pain will depend on the specific symptoms and medical history of the patient. Some common tests that may be ordered include:



1. **Blood tests:** These can help to determine if the patient has an infection or other underlying medical condition that may be causing their abdominal pain.
2. **Imaging tests:** CT scans, MRIs, and ultrasounds can help to visualize the inside of the patient's abdomen and identify any abnormalities that may be causing the pain.
3. **Endoscopy:** This procedure involves inserting a small camera into the patient's abdomen through their mouth or rectum to examine the inside of the abdomen.
4. **Laparoscopy:** This procedure involves making a small incision in the patient's abdomen and inserting a camera to visualize the inside of the abdomen.

It is important for healthcare providers to carefully consider the patient's symptoms and medical history when deciding which tests to order.

 Regenerate response

ChatGPT



Examples

"Explain quantum computing in simple terms" →

"Got any creative ideas for a 10 year old's birthday?" →

"How do I make an HTTP request in Javascript?" →



Capabilities

Remembers what user said earlier in the conversation

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ChatGPT Mar 14 Version. Free Research Preview. Our goal is to make AI systems more natural and safe to interact with. Your feedback will help us improve.

Prompt Engineering

“What is Artificial Intelligence?”

“Summarize the top five points from the ten most cited academic papers on Artificial Intelligence in bullet form.”

“Create a panel on Artificial Intelligence discussing the practical implications in healthcare. Panelist A should be a doctor, Panelist B, a risk manager, Panelist C, a healthcare lawyer, Panelist D a patient and Panelist E, a mime.”

“Research the internet for the newest articles this week on A.I. Please provide citations.”



API

(Application Programming
Interface)

APIs Will Drive AI Reach into EHRs

The screenshot displays the 'App Orchard' website interface. At the top left is the 'App Orchard' logo. A navigation bar includes 'Explore Apps' and a 'Login' button. The main content area is organized into three sections: 'Paid Apps (50)', 'Free Apps (50)', and 'All Apps (1414)'. Each section contains a grid of application cards, each featuring a logo, the app name, and the provider's name. The 'Paid Apps' section includes Hendrich II Fall Risk, Quit Manager, TC Integrated Payments, Luma Health, CheckinAsyst, and ODEZA. The 'Free Apps' section includes GetWell Loop, Copernicus Donor Care, Strata Oncology, Well365, AccessOne Registration, and Rx Support Enrollment. The 'All Apps' section includes AlertWatch:OB, Salucro Payment & Device Integration, 1800 Notify, 211 Wisconsin, and AccralWIF. A 'See More' link is present at the end of each section.

App Orchard

Explore Apps

Login

Hendrich II FALL RISK MODEL

Hendrich II Fall Risk ...
Hendrich II Fall Risk ...

Quit Manager
TEiASK

TC Integrated Payme...
TrustCommerce

lumahealth
Luma Health
Luma Health

CheckinAsyst
HealthAsyst

ODEZA
Odeza

Free Apps (50) See More

GetWell Loop
GetWellNetwork

Copernicus Donor C...
LifeLogics, Inc.

Strata Oncology
Strata Oncology

Well365
Vatica Health

AccessOne Registr...
AccessOne

Rx Support Enrollment
Point of Care Partners

All Apps (1414) See More

AlertWatch:OB
AlertWatch

SALUCRO
PAYMENT & DEVICE
INTEGRATION
Salucro Payment an

1 800 Notify
1800 Notify IVR Aut

211 Wisconsin
Get Connected. Get Help.
211 Wisconsin
United Way of Wisco...

AccralWIF
AccessOne

Source: Home - App Orchard (epic.com)



2400
RingCentral
BOOTH #3513

PEOPLE WHO GET IT

accenture

EMR Integration

Administrative Services

Guard Rails?

- FDA's role?
- Medical Device based AI
- 1995 FDA approves PAPANET.
- 1000 approved medical devices since.
- Mostly cardiology/radiology.

FDA Stance on CDS

Clinical Decision Support

Excluded from FDA jurisdiction:

- 1) not intended to acquire, process, or analyze a medical image or a signal
- (2) intended for the purpose of displaying, analyzing, or printing medical information
- (3) intended for the purpose of supporting or providing recommendations to a health care
- (4) intended for the purpose of enabling such health care professional to independently review the basis for such recommendations

Guard Rails?

- FDA declines jurisdiction unless software qualifies as a medical device
- Old ONC rules regarding Clinical Decision Support outdated.
- New proposed rules to take effect December 31, 2024 for **Predictive DSI (Decision Support Interventions)**

Guard Rails?

ONC Final Rule, Information Sharing (HTI-1)

- Quality information to determine whether to use predictive recommendation:
 - 1) What data was used to train the **predictive DSI**;
 - 2) How should the predictive DSI be used, updated, and maintained; and
 - 3) How does the predictive DSI perform using validity and fairness metrics in testing and in local data, if available.

Guard Rails?

ONC Final Rule, Information Sharing (HTI-1)

Developers must:

- employ or engage in Intervention Risk Management practices.
- practices include activities related to “risk analysis,” “risk mitigation,” and “governance.”
- Must also make summary information publicly available regarding Intervention Risk Management practices and review this information for updates annually.

Guard Rails?



Administration

OCTOBER 30, 2023

FACT SHEET: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence

Guard Rails?

ETHICS AND GOVERNANCE OF ARTIFICIAL INTELLIGENCE FOR HEALTH

WHO GUIDANCE

Guard Rails?

NIST

Information Technology Laboratory

AI RISK MANAGEMENT FRAMEWORK

Safe

**Secure &
Resilient**

**Explainable &
Interpretable**

**Privacy-
Enhanced**

**Fair - With Harmful
Bias Managed**

**Accountable
&
Transparent**

Valid & Reliable

Guard Rails? Bottom Line.

“Although the healthcare sector is heavily regulated, **no regulations** directly target the use of AI in medical devices. Most of them are now drafts or guidelines, which means they contain non-binding recommendations — a concept that is insufficient in such a high-stakes domain.”

Guard Rails? Bottom Line.

Example: Of 10 FDA-approved AI devices being used on patients today in Critical Care field:

- Only three cited published data in their authorizations.
- Just four mentioned a safety assessment
- None included a bias evaluation.
- Did anyone tell the patients AI was being used?

Guard Rails? AMA

Resolution 604 (May 2023)

- Developers of AI should ensure their products, services, systems and capabilities are subject to human authority, oversight and control.
- Organizations should be accountable for consequences related to their use of AI, including any legally cognizable injury or harm caused by their actions, unless they have taken reasonable steps to prevent harm or injury.
- Developers should ensure the transparency and traceability of their AI and protect related intellectual property by documenting key decisions made regarding the design and risk of data sets, procedures and outcomes underlying their AI.

AMERICAN BAR ASSOCIATION

STANDING COMMITTEE ON ETHICS AND PROFESSIONAL RESPONSIBILITY

Formal Opinion 512

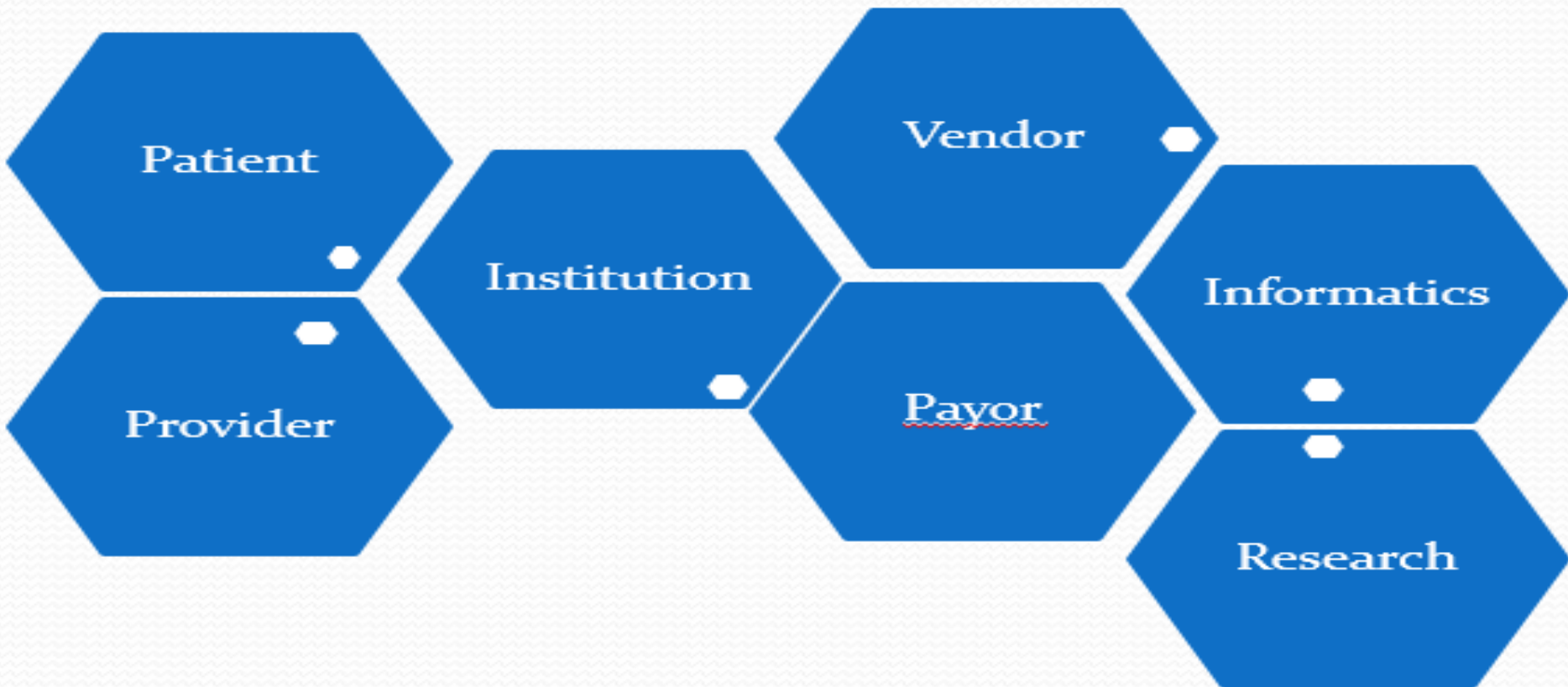
July 29, 2024

Generative Artificial Intelligence Tools

Ethics Rules apply to Gen AI

“With the ever-evolving use of technology by lawyers and courts, lawyers must be vigilant in complying with the Rules of Professional Conduct to ensure that lawyers are adhering to their ethical responsibilities and that clients are protected.”

Ethical Stakeholders – Competing Interests?



Unprecedented Risks

- Security
- Bias
- Transparency
- Disruption
- Plagiarism
- Error
- Liability

Unprecedented Risk - Security

- EPHI in AI (Google Deepmind and NHS, Univ. Chic.)
- Hacking with AI (Malware, Phishing, Automated Attacks)
- A.I. as vulnerable single-point failures.
- AI Worms!
- Deidentified data + AI + Internet and Social Media = Identified data.



WHERE'S THE DATA?



Unprecedented Risk - Security

- Where's the data?
- What's being done with the data?
- Do we need/have permission?
- Are we being informed of breaches of or by the A.I.?

Unprecedented Risk - Transparency

- Black box problem.
- Capital B and little b “bias”.
- Retention of past models.
- **Safe A.I. needs strong Information Governance to support it.**

[Int J Med Sci.](#) 2023; 20(1): 79–86.

Published online 2023 Jan 1. doi: [10.7150/ijms.77205](https://doi.org/10.7150/ijms.77205)

PMCID: PMC9812798

PMID: [36619220](https://pubmed.ncbi.nlm.nih.gov/36619220/)

Artificial intelligence in clinical decision support systems for oncology

[Lu Wang](#),¹ [Xinyi Chen](#),¹ [Lu Zhang](#),¹ [Long Li](#),¹ [YongBiao Huang](#),¹ [Yinan Sun](#),^{2,✉} and [Xianglin Yuan](#)^{1,✉}

▶ [Author information](#) ▶ [Article notes](#) ▶ [Copyright and License information](#) ▶ [PMC Disclaimer](#)

Unprecedented Risk – Disruption

- Skill degradation.
- Replacing human labor.
- Overreliance on tech.
- Disruption to existing workflows.
- Incentivizing profit over patient safety.

Disruption – Clinical Decision Making

- CDS and DSI
- Scenario 1# Clinician Intends to Use
- Scenario 2# Clinician Does not Intend to Use
- Scenario 3# Clinician Unaware of Use

How is this communicated to the patient?

If a bad outcome what would we do if just a Clinician caused harm?

Unprecedented Risk – Copyright/Plagiarism

Case 3:23-cv-03417 Document 1 Filed 07/07/23 Page 1 of 15

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22 **UNITED STATES DISTRICT COURT**
23 **NORTHERN DISTRICT OF CALIFORNIA**
24 **SAN FRANCISCO DIVISION**

25 **RICHARD KADREY, an individual;**
SARAH SILVERMAN, an individual;
CHRISTOPHER GOLDEN, an individual;

Individual and Representative Plaintiffs,

v.

META PLATFORMS, INC., a Delaware
corporation;

Defendant.

Case No.

COMPLAINT

CLASS ACTION

DEMAND FOR JURY TRIAL

Unprecedented Risk - Error

BUSINESS

Chatbots sometimes make things up. Is AI's hallucination problem fixable?

- Data Set Validity.
- Degradation – Data Set Drift.
- Different Context.
- Temperature Settings.
- Ex. Chat GPT vs. Custom GPTs

Sources:

<https://apnews.com/article/artificial-intelligence-hallucination-chatbots-chatgpt-falsehoods-ac4672c5b06e6f91050aa46ee731bcf4>

On Saturday morning, I was informed by Google Scholar that one of my books had been cited. Something about the citation puzzled me, and I therefore checked it. In a paper by three researchers (two of them tenured faculty members) at the University of _____, there is a citation to the book _____ authored by _____ and published by the _____ University Press. The problem is that no such book exists. I have not published a book with the specified title and subtitle, nor has anyone else done so. None of my books has been published with the

I proceeded to look up the non-existent volume on the Web, and I discovered that a request to a chatbot had been made a few months before the dissemination of the paper in which that imaginary book is cited. The request asked the chatbot for references to works on legal positivism and natural-law theories. The chatbot provided three references, including the one to the non-existent book by _____ The researchers at the University of _____ apparently made no effort to verify the actuality of that book, and they obviously made no effort to read it. Instead, they simply cited it for the edification of their readers.

Unprecedented Risk - Liability

- Vendor liability— Learned Intermediary
- BUT -- Dr. G case, Cerner case
- Indemnification
- Institution setting the standard of care?
- Criminalization for deviation from AI?
- Informed Consent

Dr. G case

- Skounakis v. Sotillo, A-2403-15T2 (N.J. Super. Ct. App. Div. Mar. 19, 2018).
- Did coded advice comport with standard of care?
- No technical expert needed!
- One state, many others will default to provider liability!

Low v. Cerner case

- Low v. Cerner Corp., No. 20-2270. United States Court of Appeals, Fourth Circuit.
- Default setting for timing or orders. Docs unaware.
- Clinicians settled, plaintiff proceeded against EHR Vendor on Products Theory.
- Software Defects could be a cause of plaintiff's injuries in addition to clinical acts

Sampson v. Heartwise

case

- Patient's family aware of an AI tool used at facility to assess for heart conditions and risks. (Saw billboards, advertisements and brochure.)
- Plaintiff sues both clinicians and software vendor.
- Claims against software vendor sound in direct negligence and fraud.
- Court dismisses negligence claim (due to clinician involvement) but sustains a claim for fraud against vendor.

Informed Consent and A.I.

Example: A drug at a certain dosage is recommended by AI platform to a clinician.

- Does clinician owe a duty to disclose use of AI?
- How can informed consent be provided if clinician does not understand how A.I. works? What is developer does not fully understand?
- What if clinician disagrees with A.I.
- Informed Consent about AI itself (All these risks?)
- Right to opt out?

Risk Guidance

Assess:

- 1) Is A.I being used in your practice/client's facility? (Hint: Yes.)
- 2) If so, formally or informally?
- 3) Catalog applications

Risk Guidance

Informal use.

Policies

Tracking

Reporting

Formal use.

Vetting

Security Concerns. BAAs

Information governance

Documentation

Information Governance

Multidisciplinary (Patients, Clinical, Tech, Legal, Risk, Compliance, Quality, Ethics)

Defined, empowered, funded.

Providing Oversight During Life Cycle:

Product Assessment

R&D phase

Adoption

Ongoing Monitoring

End of LifeCycle

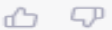
LAST YEAR

CB

do artificial intelligence applications pose risks to healthcare organizations?



Yes, artificial intelligence (AI) applications can pose risks to healthcare organizations if they are not properly designed, implemented, and monitored. While AI has the potential to revolutionize healthcare by improving patient outcomes and reducing costs, there are also several risks to consider.



One risk is the potential for AI algorithms to produce biased results, which can lead to disparities in healthcare outcomes for different groups of patients. For example, if an AI algorithm is trained on a dataset that is not representative of the broader population, it may produce recommendations or diagnoses that are inaccurate or inappropriate for certain patient groups.

Another risk is the potential for AI to make mistakes that can harm patients. For example, if an AI algorithm is designed to identify certain medical conditions, it may miss important symptoms or misdiagnose a patient, leading to delayed or ineffective treatment.

In addition, the use of AI in healthcare raises important ethical and privacy concerns, such as who has access to patient data and how that data is used.

To mitigate these risks, healthcare organizations need to carefully evaluate AI applications before implementing them and ensure that they are designed and tested to produce accurate and unbiased results. They also need to closely monitor the use of AI in patient care and be prepared to address any issues that arise. Finally, healthcare organizations need to prioritize transparency and patient privacy, ensuring that patients are fully informed about how their data is being used and protected.

NOW



You

do artificial intelligent applications pose risks to healthcare organizations?



Which response do you prefer?

Your choice will help make ChatGPT better.



Response 1

Artificial intelligence (AI) applications have become increasingly prevalent in healthcare organizations, offering numerous benefits such as improved diagnosis accuracy, patient outcome predictions, and operational efficiencies. However, their integration into healthcare also poses various risks that organizations must manage. Here are some of the key risks associated with AI in healthcare:

1. Data Privacy and Security Risks

AI systems often require access to vast amounts of sensitive and personal health data. The collection, storage, and processing of this data pose significant privacy risks if not properly managed. Breaches can lead to exposure of patient information, potentially violating regulations like HIPAA (Health Insurance Portability and Accountability Act) in the United States.

2. Bias and Fairness Concerns

AI models can perpetuate or even exacerbate biases present in their training data. If the data used to train AI systems is not representative of the diverse patient population, these systems may deliver biased outcomes. This can affect minority groups adversely



Response 2

Artificial intelligence (AI) applications in healthcare offer significant potential to improve patient outcomes, streamline operations, and reduce costs. However, these technologies also introduce a range of risks and challenges that healthcare organizations must navigate. Some of the primary concerns include:

- 1. Data Privacy and Security:** AI systems often require access to vast amounts of personal health information. Protecting this data from breaches and unauthorized access is crucial, given the sensitive nature of health records. Cybersecurity vulnerabilities in AI systems could lead to significant breaches of patient confidentiality.
- 2. Bias and Fairness:** AI models can inadvertently perpetuate or even exacerbate biases present in their training data. This can lead to unequal care delivery or misdiagnoses, particularly for underrepresented groups in the data. Ensuring AI systems are fair and unbiased is a major challenge.
- 3. Regulatory Compliance:** Healthcare is a highly regulated sector, with stringent requirements for patient data handling, medical device approval, and more. AI applications must comply with regulations such as HIPAA in the US, GDPR in Europe, and others,

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Thank you for your attendance!

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AI in Healthcare: Legal and Ethical Challenges

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