

AI in Healthcare: *The Shadows*



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Conflicts

- Nothing to disclose

The Shadows



Edward Hopper, **Rooms by the Sea** (1951)

Outline

- Analytic versus generative AI (refresh)
- Accuracy, equity, and regulatory challenges in AI
 - Analytic AI *advances*
 - Generative AI *challenges*
- Correcting the sins of its EHR predecessor?: Where generative AI in healthcare is going
- What do I want the nursing profession, clinicians, regulators, and patients to be thinking about and anticipating?

PREDICTIVE/ANALYTIC AI

- Age
- Sex
- Comorbidities
- Lab values
- Etc.



- Predicted probability of diabetes
- Predicted class (diabetes/no diabetes)
- Risk “score” for diabetes
- Etc.

GENERATIVE AI (LLM)

KA

You

Come up with a study name acronym for research that will investigate CRE carriage, a drug-resistant bacteria, in hospitalized patients



ChatGPT

An appropriate study name acronym for research focused on investigating Carbapenem-resistant Enterobacteriaceae (CRE) carriage in hospitalized patients could be "HICARE":

Hospitalized
Infection
Carbapenem-resistant
Antibiotic
Resistant
Enterobacteriaceae

This acronym, HICARE, not only encapsulates the focus of the study (CRE carriage in hospitalized patients) but also implies a commitment to care and attention in a healthcare setting.

Predictive/Analytic AI

Challenges and Encouraging Advances

Algorithm Accuracy (Performance)

Epic's AI algorithms, shielded from scrutiny by a corporate firewall, are delivering inaccurate information on seriously ill patients

STAT



By [Casey Ross](#)  July 26, 2021

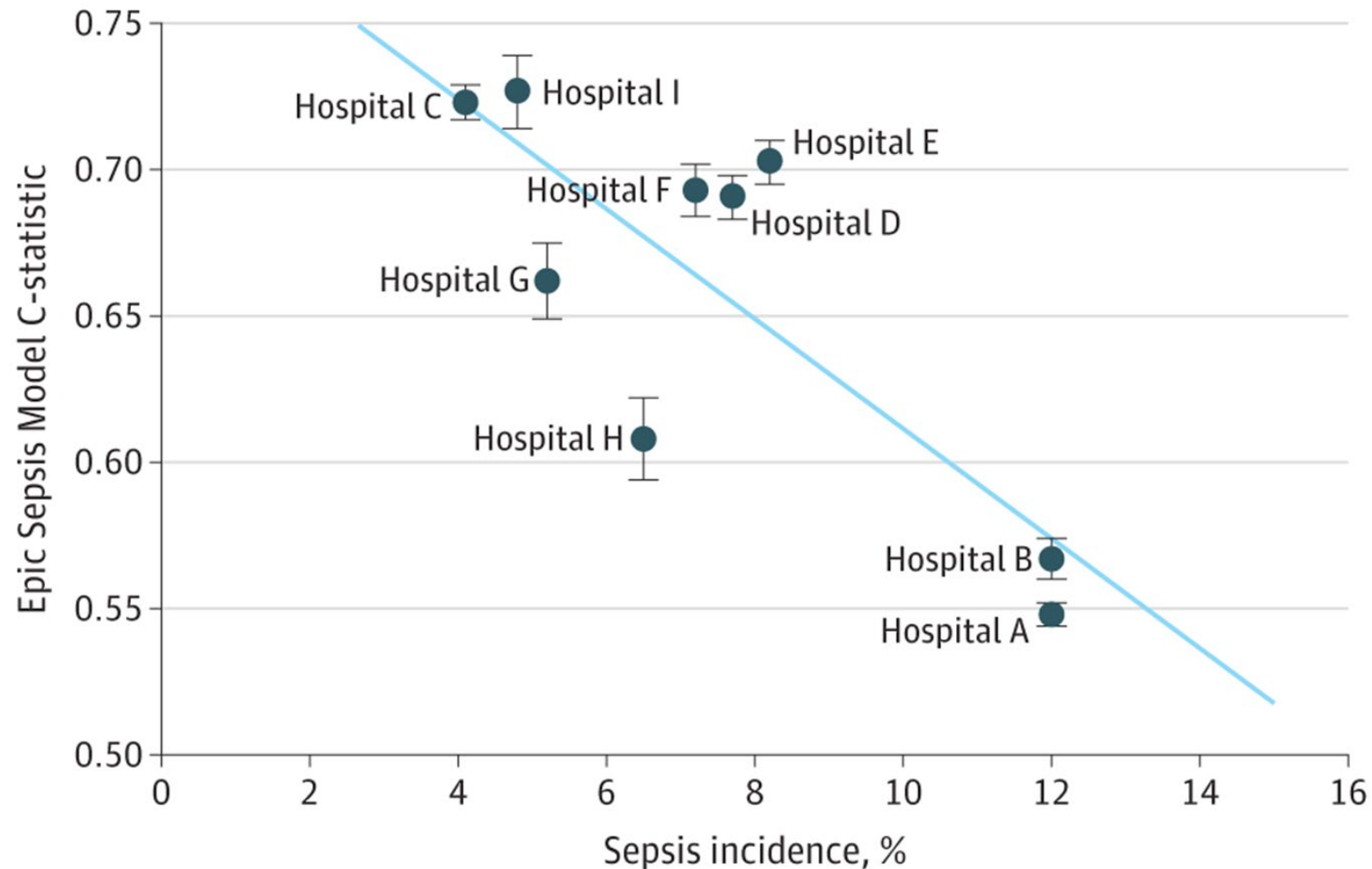
Algorithm Accuracy

There are two big takeaways:

- a. Of the 2,552 patients with sepsis, ESM only generated sepsis alerts for 843 (33 percent). They missed 67 percent of the people with sepsis.
- b. Of the 6,971 ESM sepsis alerts, only 843 (12 percent) were correct; 88 percent of the ESM sepsis alerts were false alarms, creating what the authors called “a large burden of alert fatigue.”

Reiterating, ESM failed to identify 67 percent of the patients with sepsis; of those patients with ESM sepsis alerts, 88 percent did not have sepsis.

Algorithm Accuracy



Lyons et al., Factors Associated With Variability in the Performance of a Proprietary Sepsis Prediction Model Across 9 Networked Hospitals in the US. JAMA Intern Med. 2023.

FDA Regulation

Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 28, 2022.

The draft of this document was issued on September 27, 2019.

JAMA®

Viewpoint

January 5, 2023

Clinical Algorithms, Antidiscrimination Laws, and Medical Device Regulation

Katherine E. Goodman, PhD, JD¹; Daniel J. Morgan, MD, MS^{1,2}; Diane E. Hoffmann, JD, MSc³

Algorithmic Bias/Equity

Dissecting racial bias in an algorithm used to manage the health of populations

ZIAD OBERMEYER , BRIAN POWERS, CHRISTINE VOGELI, AND SENDHIL MULLAINATHAN  [Authors Info & Affiliations](#)

SCIENCE • 25 Oct 2019 • Vol 366, Issue 6464 • pp. 447-453 • DOI: [10.1126/science.aax2342](https://doi.org/10.1126/science.aax2342)

The U.S. health care system uses commercial algorithms to guide health decisions. Obermeyer *et al.* find evidence of racial bias in one widely used algorithm, such that Black patients assigned the same level of risk by the algorithm are sicker than White patients (see the Perspective by Benjamin). The authors estimated that this racial bias reduces the number of Black patients identified for extra care by more than half. Bias occurs because the algorithm uses health costs as a proxy for health needs. Less money is spent on Black patients who have the same level of need, and the algorithm thus falsely concludes that Black patients are healthier than equally sick White patients. Reformulating the algorithm so that it no longer uses costs as a proxy for needs eliminates the racial bias in predicting who needs extra care.

Algorithmic Bias/Equity






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MEDICINE AND SOCIETY



Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms

Authors: Darshali A. Vyas, M.D. , Leo G. Eisenstein, M.D. , and David S. Jones, M.D., Ph.D.  [Author Info & Affiliations](#)

Published June 17, 2020 | N Engl J Med 2020;383:874-882 | DOI: 10.1056/NEJMms2004740 | [VOL. 383 NO. 9](#)

Algorithmic Bias/Equity



U.S. Department of
Health and Human Services
Office of Minority Health

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Shedding Light on Healthcare Algorithmic and Artificial Intelligence Bias



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Meetings Examine Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare

Anti-Discrimination Regulation



U.S. Department of
Health and Human Services

Enhancing the health and well-being of all Americans

**HHS Issues New Rule to Strengthen
Nondiscrimination Protections and Advance Civil
Rights in Health Care**

New HHS Regulation (May 2025)¹: For tools with protected trait (race, sex, color, age, national origin, disability) inputs, must exercise “reasonable efforts to mitigate the risk of discrimination.”

¹ - <https://www.hhs.gov/about/news/2024/04/26/hhs-issues-new-rule-strengthen-nondiscrimination-protections-advance-civil-rights-health-care.html>



Perspective

Preparing Physicians for the Clinical Algorithm Era

Katherine E. Goodman, J.D., Ph.D., Adam M. Rodman, M.D., M.P.H., and Daniel J. Morgan, M.D.

“The U.S. government recently took steps to ensure that clinical decision support algorithms are safe for clinical use. The next and larger step will be teaching physicians how to use the algorithms effectively.”



Generative *AI Challenges*

The Wild West of Clinical Generative AI

Clinical Decision Support Software

Guidance for Industry and Food and Drug Administration Staff

Document issued on **September 28, 2022.**

The draft of this document was issued on September 27, 2019.

ChatGPT was launched on **November 30, 2022**, by San Francisco-based OpenAI (the creator of the initial GPT series of large language models; DALL·E 2, a diffusion model used to generate images; and Whisper, a speech transcription model).



Wikipedia

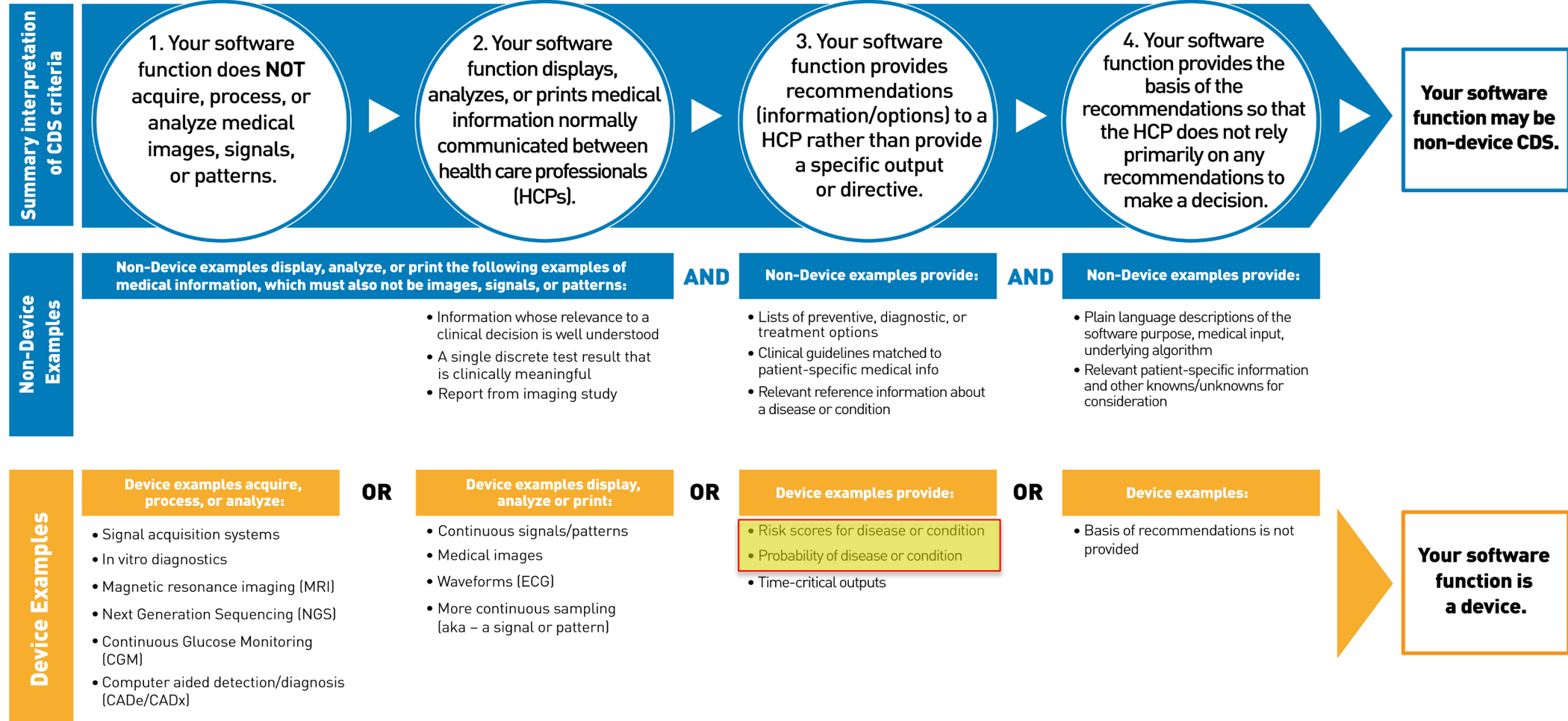
<https://en.wikipedia.org/wiki/ChatGPT>

[ChatGPT - Wikipedia](https://en.wikipedia.org/wiki/ChatGPT)

Your Clinical Decision Support Software: Is It a Device?

The FDA issued a guidance, Clinical Decision Support Software, to describe the FDA's regulatory approach to Clinical Decision Support (CDS) software functions. This graphic gives a general and summary overview of the guidance and is for illustrative purposes only. Consult the guidance for the complete discussion and examples. Other software functions that are not listed may also be device software functions. *

Your software function must meet all four criteria to be Non-Device CDS.



January 29, 2024

AI-Generated Clinical Summaries Require More Than Accuracy

Katherine E. Goodman, JD, PhD^{1,2}; Paul H. Yi, MD³; Daniel J. Morgan, MD, MS^{1,4}

Suspected myocardial infarction: "... 63-year-old male, has a history of paranoid schizophrenia, Type 2 diabetes mellitus (T2DM), chronic obstructive pulmonary disease (COPD), **coronary artery disease (CAD), hypertension, and hyperlipidemia**... Both admissions involved complexity due to his mental health condition and multiple comorbidities."

Suspected pneumonia: "... 63-year-old male, was admitted **due to fever and altered mental status**. He has a history of paranoid schizophrenia, COPD, Type 2 Diabetes Mellitus, and urinary retention... Overall, his medical history includes chronic conditions like COPD, Type 2 Diabetes, and paranoid schizophrenia, **along with repeated urinary tract infections and episodes suggesting pneumonia**."

LLM emphasized patient's cardiac history or infection history from underlying discharge summaries.

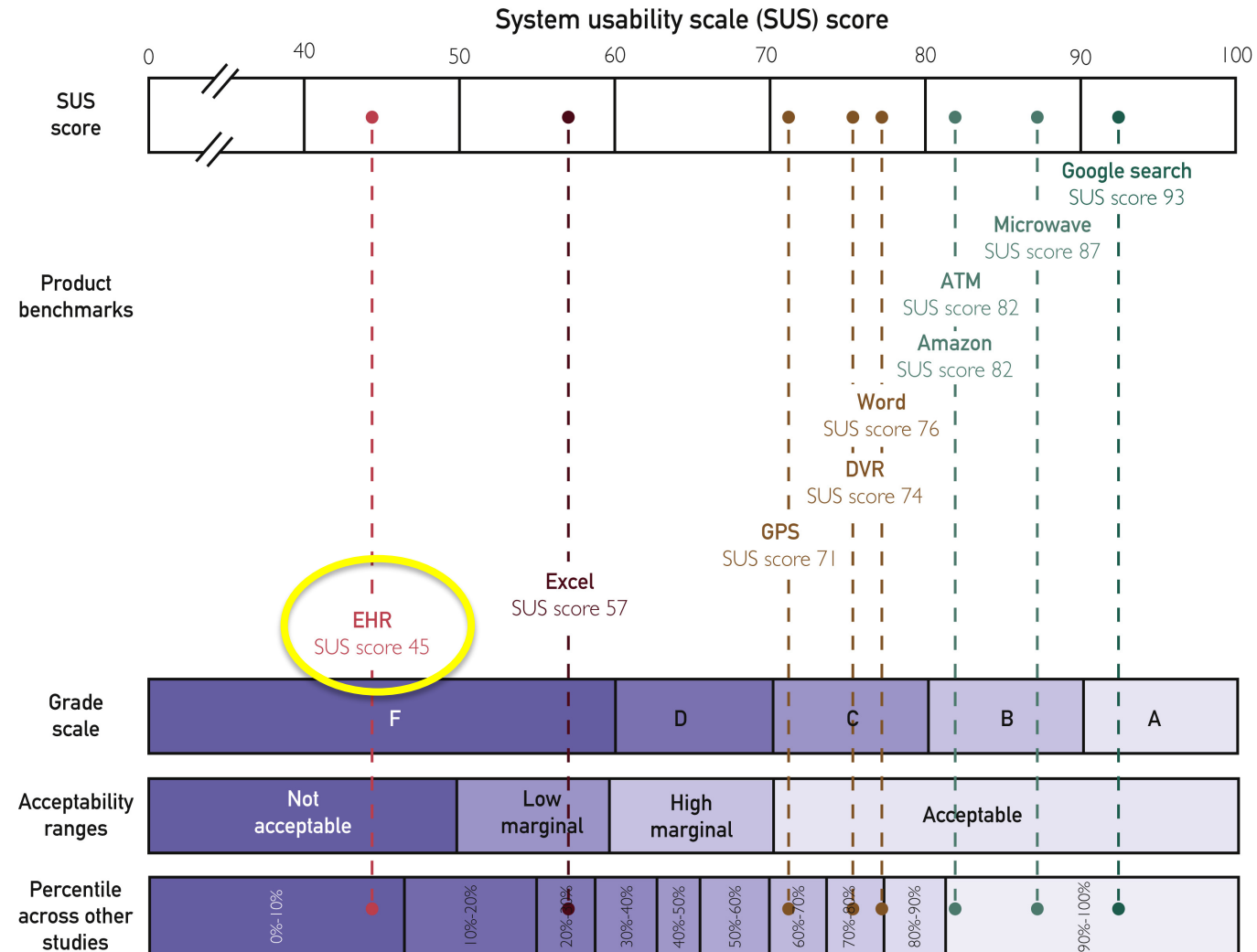
***Structural* Equity Considerations**

- AI scribes may optimize for billing/revenue
- Further exacerbation of “have” and “have not” facilities (already occurring, but amplified)
- Other AI tools generally require on-site expertise; out of reach for lower-resourced institutions
- Follow-on implications for patient care

Where Generative AI May Be/Is Going

Clinician- and Patient-Facing Examples

1) EHR Information Summarization/Extraction



EHR Information Summarization/Extraction

H&P Note

Name: John

Smith Admission Date: 2/12/2023 Discharge Date: 2/14/2023 Date of Birth: January 1, 1960 Sex: M Service: MEDICINE Allergies: No Known Allergies / Adverse Drug Reactions Chief

Complaint: Altered Mental Status Major Surgical or Invasive Procedure:

None History of Present Illness: Mr.

Smith is a 63-year old male with history of schizophrenia with most recent ED visit 10/22, COPD, DM, mechanical falls most recently in Aventis

NH and s/p negative syncope workup in ___, history of urinary retention s/p indwelling foley in ___, admission in ___ for sepsis from pneumonia, presenting with complaints of fever and altered mental status. Mr.

Smith presented to the ED from his group home after reportedly being febrile yesterday. The group home care staff changed his foley yesterday and noted that his mental status was altered this morning.

Seen in December on the

10th by Dr. Reed for evaluation of need for chronic foley which was placed in late December after presented to the ED after a fall and was found to be incontinent (prior to this, he had no problems voiding) and have obstructive uropathy. Noted to have a hypersensitive bladder with normal compliance, terminal detrusor overactivity, no obstruction, and was able to empty bladder completely despite over activity. T

“the patient was found alone at a restaurant, which implies he was living independently or at least not in a care facility at the time of the incident. There is no mention of a recent stay in any type of long-term care facility in the history provided.”

EHR Information Summarization/Extraction

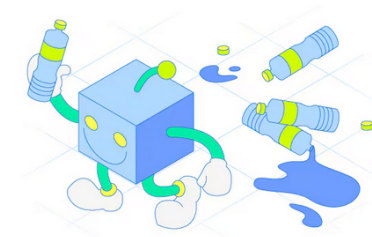
- Is using LLMs to “fix the sins” of the EHR a good use of money and environmental resources?

The New York Times

*Hungry for Energy, Amazon, Google
and Microsoft Turn to Nuclear Power*

The Washington Post

Democracy Dies in Darkness



POWER GRAB

**A bottle of water per email: the hidden
environmental costs of using AI chatbots**

2) Patient-directed Interpretation

Beginning April 5, 2021, all patient care information including lab results, pathology and test results will be available to patients in MyChart as soon as posted. This is a mandate of the 21st Century Cures Act designed to place more control of treatment information in the hands of the patient. Inova's goal is to embrace patients and their families as integral members of the care team.



She added: 'I checked the portal on the hike, and that's when I saw words like invasive, ductal, carcinoma, malignant. And I was like, 'Those words sound like cancer words.'

2) Patient-directed Interpretation

Startup launches service that translates radiology reports into 5th-grade reading level

- **Do we really want AI filling this gap for patients?**
- **Provider “2nd Audience” Liability?:** Second read of radiology reports, (possibly) imaging; who owns those data?

3 (of Many) Questions that Occupy My Brain on Long Commutes:

- 1) What **are** the aspects of healthcare and medicine that we think should be reserved for humans? Increasingly, this is a values question more than a technological question.
- 2) How do we prevent an LLM clinical arms race (greater automation → decreased appt lengths/increased scheduling → net-neutral long-term improvements)?
- 3) What is the appropriate model for regulating LLMs? (As a person? As a device?)