GOVERNANCE, REGULATION, AND ACCOUNTABILITY OF AI IN HEALTH

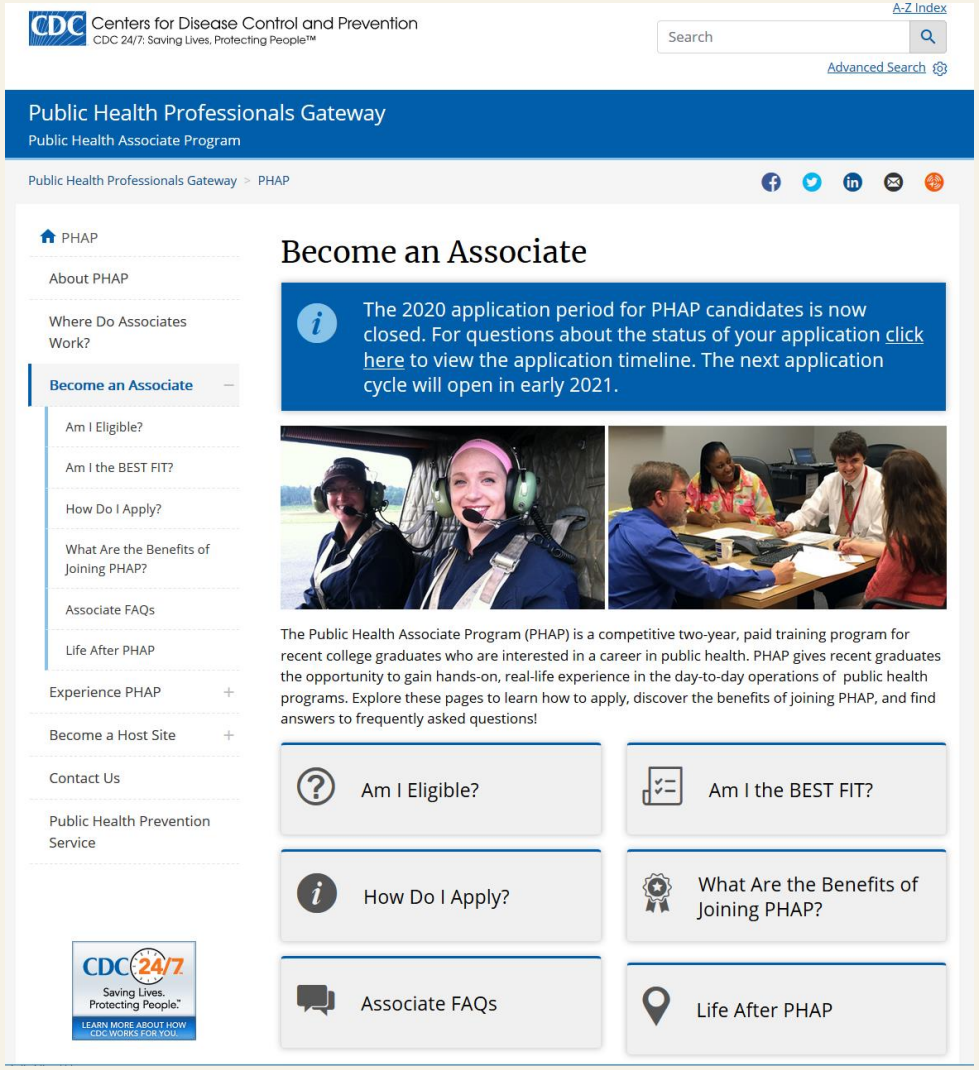
Alka Menon, PhD

Yale University

National Dialogues on Behavioral Health

November 10, 2026

CDC BACKGROUND, LOCAL PUBLIC HEALTH: TB CONTROL







Alka Menon
Yale Sociology

Lynn Fiellin
Yale School of Medicine

Xenophon Papademetris
Yale School of Medicine

Christian Kastner
Carnegie Mellon School of Computer Science

RESEARCH TEAM

- Sociologist of medicine, technology and society at Yale University
- Research how medicine and society shape one another
- National Science Foundation-funded project on designing policy to hold AI software systems accountable (CISE/CCF 2131466)
- Teach a class on AI, Medicine and Society

ONE-THOUSAND-FOOT VIEW FROM SOCIOLOGY

- Book on AI, Medicine and Society (with Xenophon Papademetris and Emily Johns)
- Have been researching AI in health contexts with computer scientists, biomedical engineers, researchers in internal medicine and public health since 2019
  - Retina screening (diabetic retinopathy) to prevent blindness
  - Substance abuse prevention in teens through serious game play
    - Concerns about bringing to being the future one is trying to prevent with vaping or smoking

AI IS COMING, BUT IT'S GOING TO GET MESSY.



What would it take to actually use AI to improve health?



MAGIC WAND

- Medical trilemma:
  - High Quality
  - Short Delays
  - Low Cost
- Ordinarily you can have, at most, any two.
- AI will allow all three, plus quality of life for physicians.

AI, MEDICINE, AND SOCIETY: BOOK



- If in a sentence you can replace the word ‘AI’ with the word ‘magic’ and it still makes sense, be skeptical.
- Adoption and implementation of previous technologies into society can teach us something about how to integrate AI into healthcare.

SHOULD AI BE INTEGRATED INTO THE HEALTHCARE SYSTEM, AND HOW?

- “Can” is a moving target; centrally questions of “should,” which is a critical part of AI governance
- My goal is to create space to think what would make AI useful to you and to advance goals that you have
  - Realize new goals
- Think to yourself as you listen today:
  - What are the problems you’re trying to solve?
  - What are the obstacles to solving them?

TALK OVERVIEW

- AI and regulation
- Relationship between humans and AI
  - Governance beyond regulation
  - How people (“humans”) are involved: Sociotechnical systems
- Other considerations: Thoughts from my pre-health students
- Conclusions

AI AND REGULATION



HARD LAW VERSUS SOFT LAW

- We tend to focus on black letter law: EU AI Act, EU GDPR, COPPA, HIPAA
  - This is “hard” law, with enforcement mechanisms behind it
- But “soft” law are key in medicine and with rapidly changing technology
  - Guidelines and standards (e.g., Apgar score)
  - Health insurance coverage and administration decisions (i.e., pre-authorization) is soft law
    - Minimal transparency requirements
  - Court cases and settlements: liability

Yale

REGULATORY LANDSCAPE FOR AI

- Not much hard law/regulation: EU AI Act, EU GDPR, California's Privacy Act
- Movement on the soft law: standards from the International Standards Organization, National Institutes of Standards, Food and Drug Administration, Consumer Trade Association, medical device industry
  - None of this directly touches the foundational large language models (LLMs) that are being repurposed with many alternatives

WHAT ARE WE REGULATING?

- The use of the tool
  - Traditional medical device regulation
- The technology
  - Horizontal regulations: EU AI Act

WHERE ARE WE REGULATING?

- In the territory which the government controls.
  - Territoriality.
- Wherever the digital footprint of the residents of my country are found.
  - Extraterritoriality.
  - EU GDPR, AI Act.
  - Internet does not respect physical boundaries.
  - Domination by large US-based tech companies.

EU VS. US

FDA has dual role:

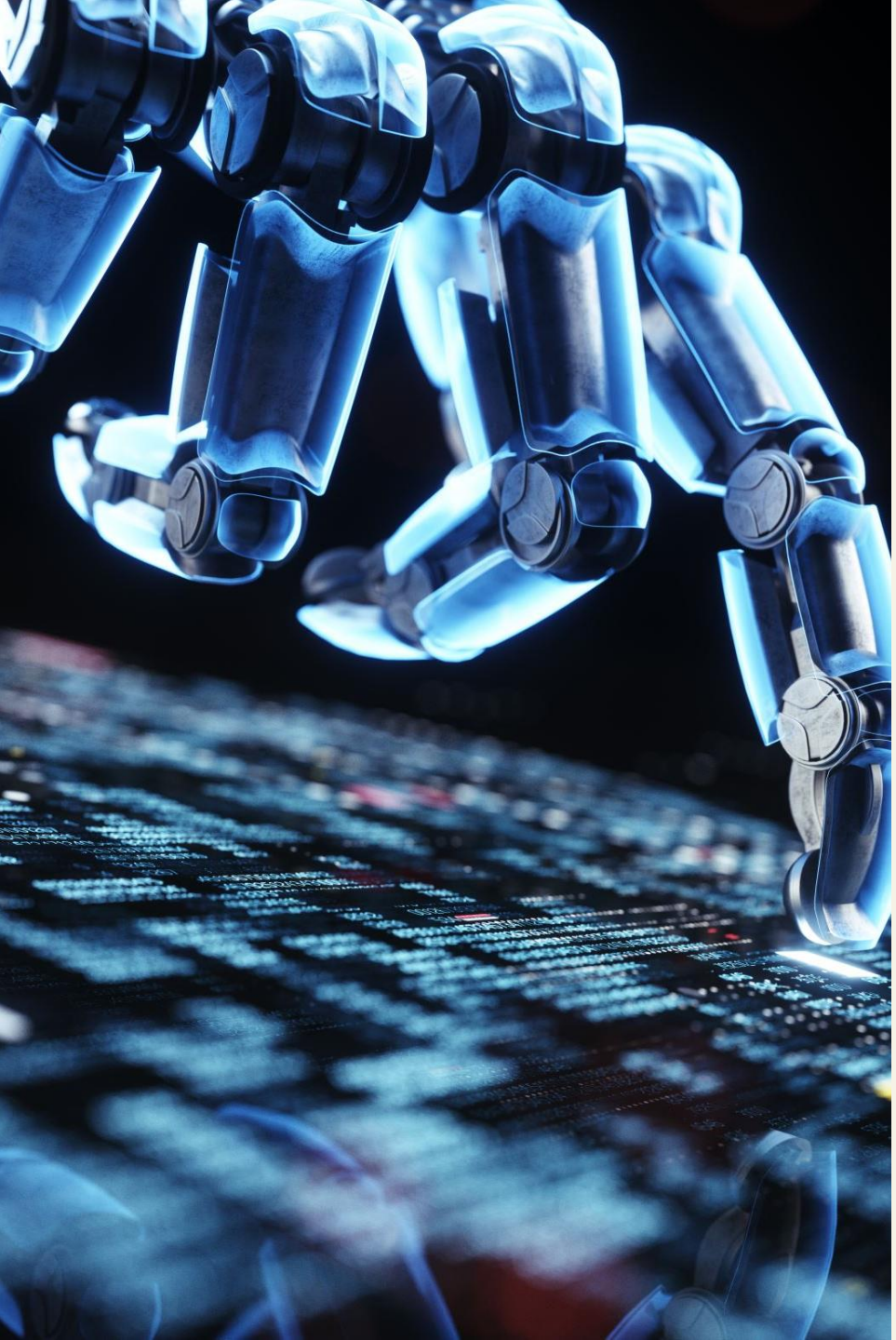
- Review of devices prior to entering the market
- Market regulator – enforces post market

EU

- Review done by authorized, private companies – Notified Bodies
- Government authorities regulate the market

BUT MANY AI-CAPABLE DEVICES DO NOT REQUIRE FDA OVERSIGHT

- Wearables
- Clinical decision support tools
- Ambient AI and administrative processing
- Or manufacturers pursue a less scrutinized use case: screening tool versus diagnostic tool



EXAMPLE: MENTAL HEALTH CHATBOT CHALLENGES

U.S. FDA regulation pathway unclear for large language models

- Clinical trial design and cost

Changes in AI model capability

- Bandwagon effect

Integration into existing payor structures (e.g., employers, insurance)

https://www.statnews.com/2025/07/02/woebot-therapy-chatbot-shuts-down-founder-says-ai-moving-faster-than-regulators/

RELATIONSHIP BETWEEN HUMANS AND AI



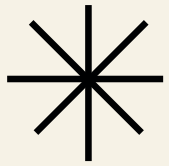
Technical capability and social consequences are wrapped together: Anticipate the social consequences

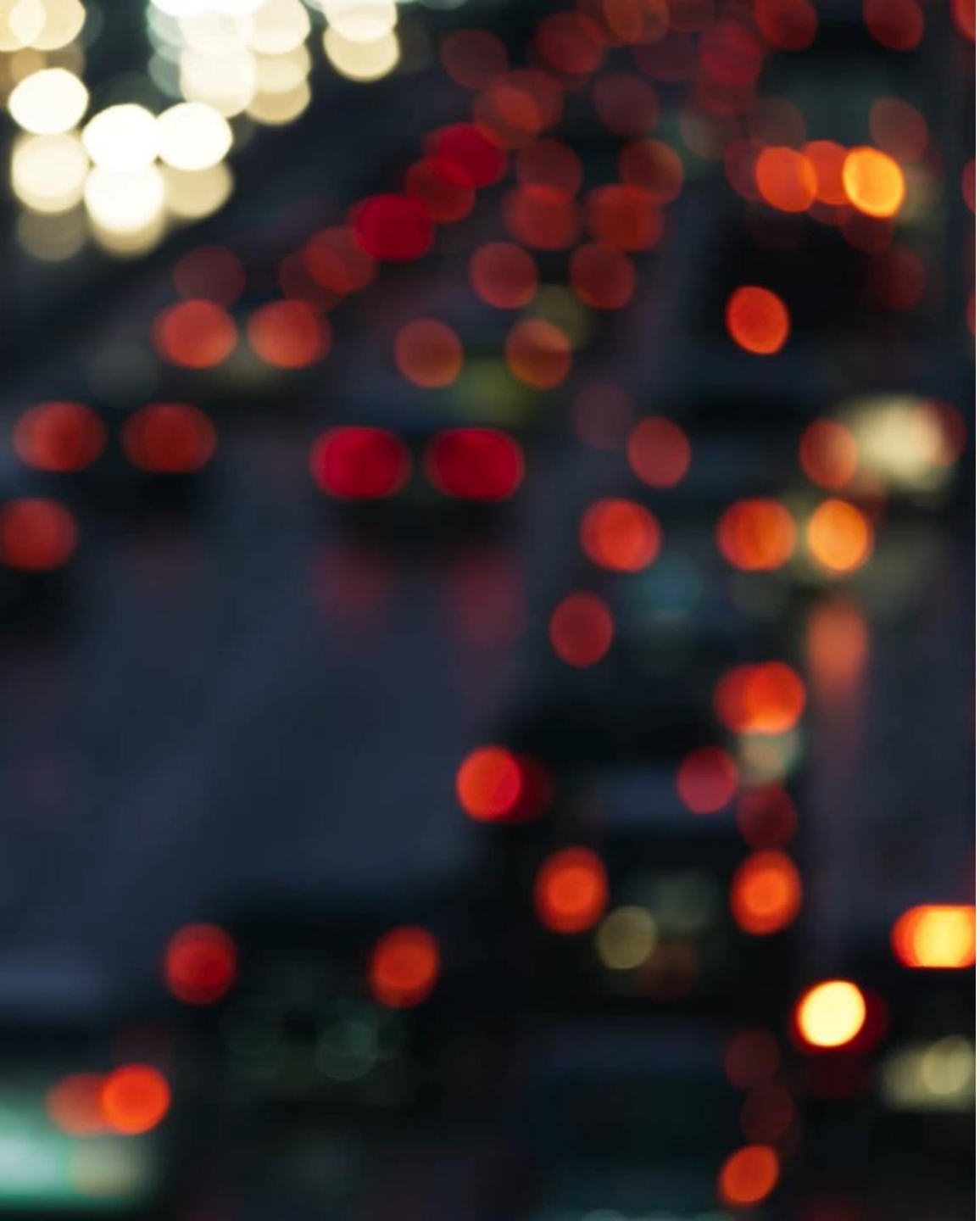
ACCOUNTABILITY FROM SOCIOLOGY

- AI as a large, complex sociotechnical system
  - Foundational models (e.g., ChatGPT, Claude) could be thought of as infrastructure
  - Smaller AI systems integrate into the complex, sociotechnical system that is the healthcare system.
- Sociotechnical Systems
  - Human + Technology
  - Seeing the human and the social component as part of one system, and looking at vulnerabilities and opportunities on both sides

ROLE OF PEOPLE IN AI SYSTEMS

1. “Human-in-the-loop” for oversight or as monitor
   - What information or skills do people need to have to provide meaningful review?
2. Human as backup
   - What skills does a person need?
3. Human as partner
   - Can AI complement the skills of a person? Triage? Organize?
4. Human as replaced
   - Human as a bottleneck or step in the clinical workflow
5. Human as antagonist
   - How could someone turn this tool to a different, nefarious end?

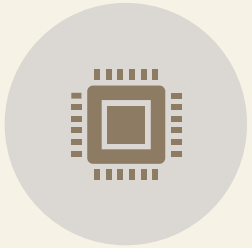




MANAGING RISK IN SOCIOTECHNICAL SYSTEMS

- Large complex systems → unintended consequences
- Normal accidents (Perrow 1984, Normal Accidents): complexity and tight coupling of technical systems parts inevitably lead to failure
  - Air traffic as low risk technical system, or error reducing (see also Vaughan 2021)
  - What makes high-reliability sociotechnical systems so safe? (In air traffic control, it's a lot of redundancy.)

CHANGE IN SOCIO-TECHNICAL SYSTEMS



Built on top of existing (aging) infrastructures and organizations: Patching of new onto old → lag



Design and implementation of tech innovation engenders tension between standardization and customization to local particularities



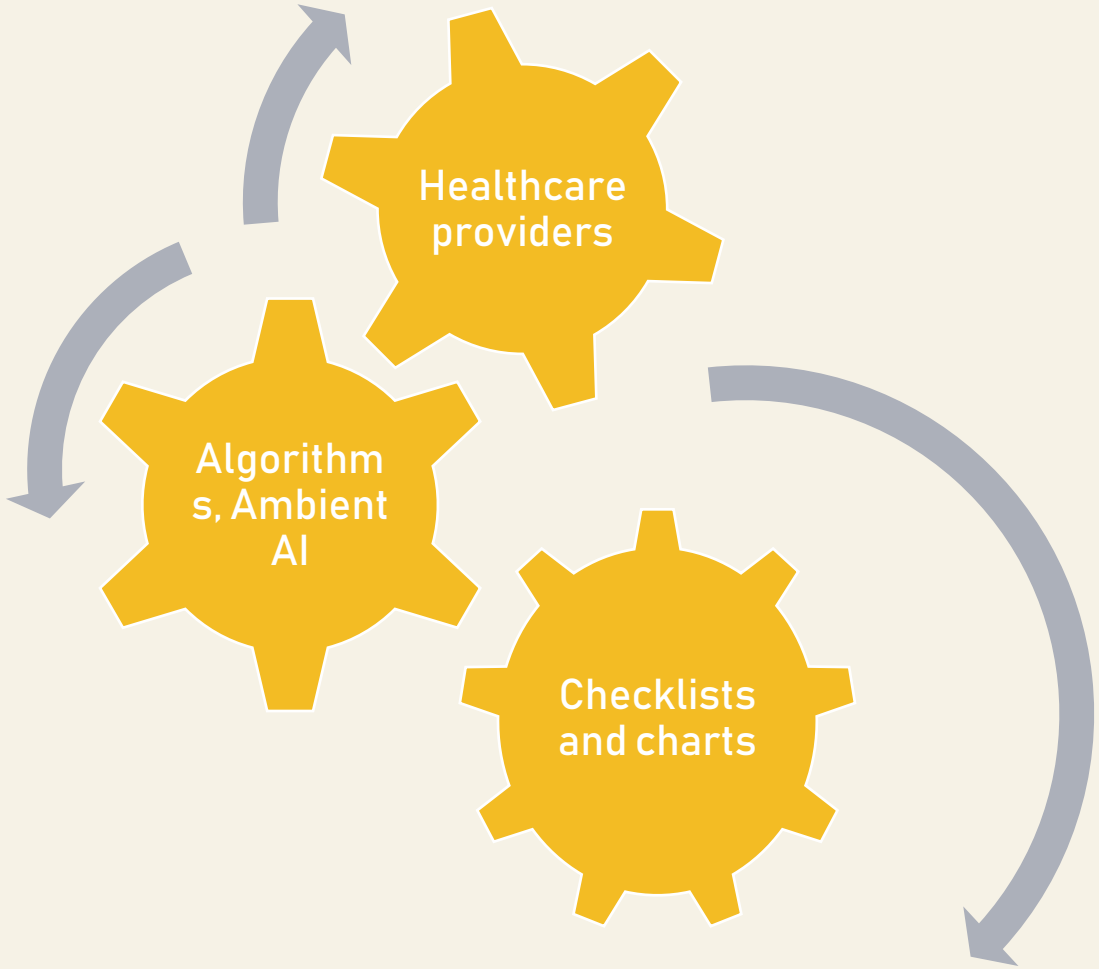
Necessity of improvisation and repair, leading to system persistence



Role of people in problem-solving: resilience, reliability, redundancy to create flexibility in system

MORE MICRO

- How are the “humans-in-the loop” imagined at the design phase, and how might they change over time?
- Discrepancy between design and implementation
- Benchmarking of AI abilities to the skills of current healthcare providers, which will not be the same in the future
- The context for adapting use cases



OTHER CONSIDERATIONS



MY STUDENTS HOPE YOU ARE THINKING ABOUT...

-Loop of deskilling

-Counting invisible labor that will become visible when AI doesn't do it

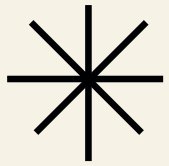
-Building a better interface between AI and physicians

-Environmental and sustainability concerns

-Generational differences: AI natives as more skeptical than older people

-Thinking long term

-Taking stakeholder/ordinary people's views in mind



MY STUDENTS HOPE YOU ARE THINKING ABOUT...

-The potential of AI to worsen mental health

-Tackling persistent social biases (along the lines of gender, race, class)

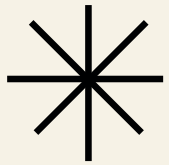
-Keeping humans in decision-making positions with oversight over algorithms

-Patient privacy

-Building better bridges between AI and healthcare workers

-Integrating AI into health systems for social impact

-Testing AI systems in situ



CONCLUDING THOUGHTS

Previous technological integrations offer lessons for approaching AI in healthcare today.

- Sociotechnical system
  - Intervening on both the human and the technical side of the equation to integrate a model into a given context
- Shadow versus reality

Should we integrate AI? For what purpose? With what relationship to existing workers and workflows? And with what goal for patient health outcomes?

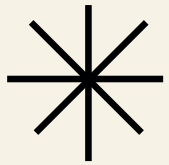
MORE RESOURCES

Chen, Brian J. and Jacob Metcalf. Explainer: A Sociotechnical Approach to AI Policy.

Vaughan, Diane. 2021. Dead Reckoning: Air Traffic Control, System Effects, and Risk.

Nelson, Alondra. The mirage of AI deregulation.

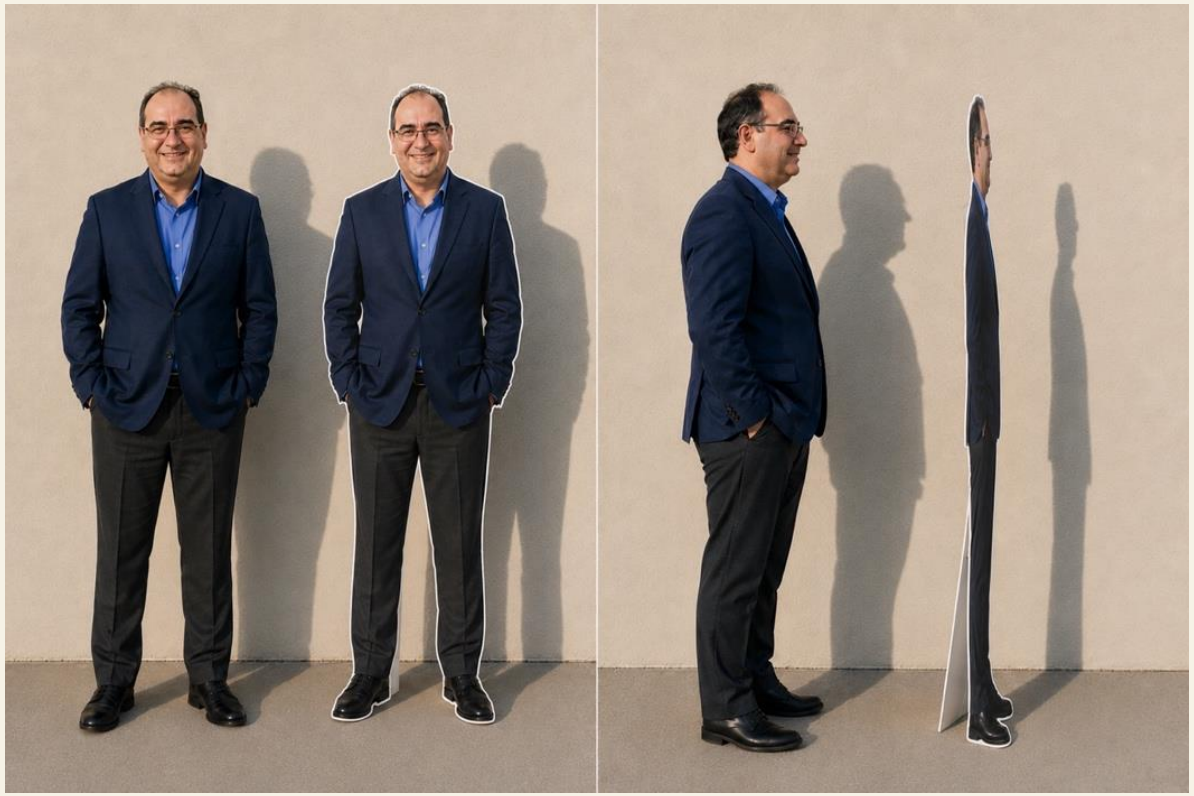
Email me for more! Alka.menon@yale.edu



BONUS THEME: SHADOWS VS. REALITY



AI IS A MASTER OF SHADOWS (REPRESENT-ATIONS)



A real human, a cardboard version of a human, and their shadows. Left: front view of a human and a cardboard version of the human facing the camera, casting the same shadow on the wall behind them. Right: human and cardboard are rotated by 90 degrees. The shadows are now very different. *This figure was created using generative AI tools (figure: Xenophon Papademetris).*

KNOWING SOMETHING ABOUT THE REPRESENTATIONS IS IMPORTANT IN MOORING AI TO THE REALITY OF PATIENT OUTCOMES.

