Calculated Risks

ENSURING ACCURACY AND EQUITY IN HOSPITAL RESOURCE ALLOCATION SOFTWARE

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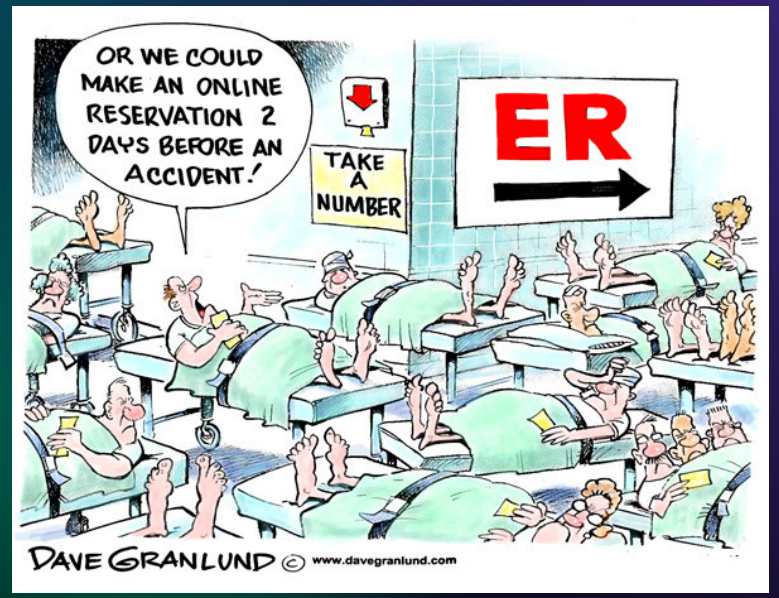
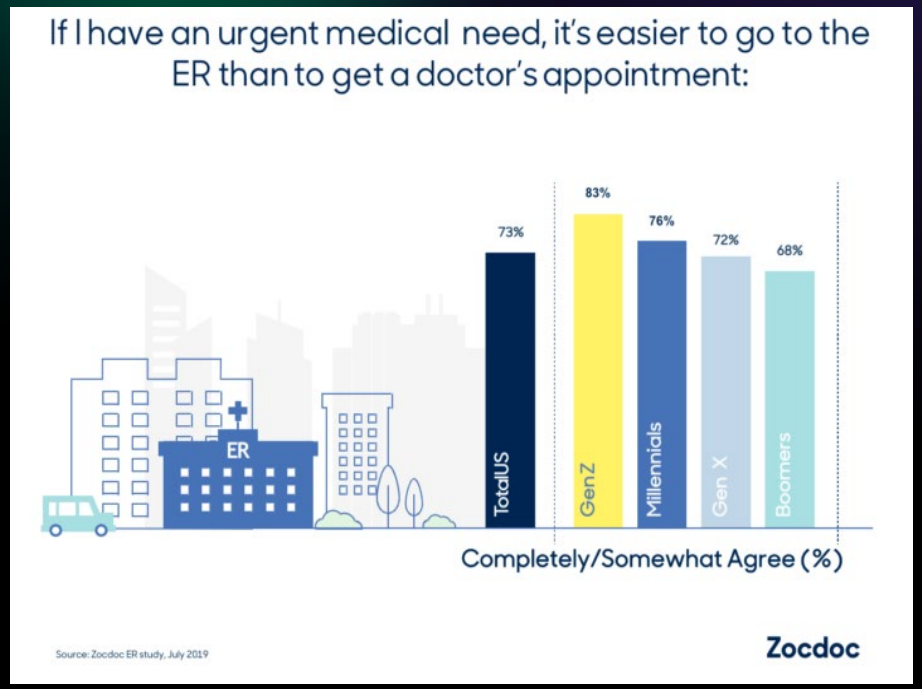
IEEE WISE

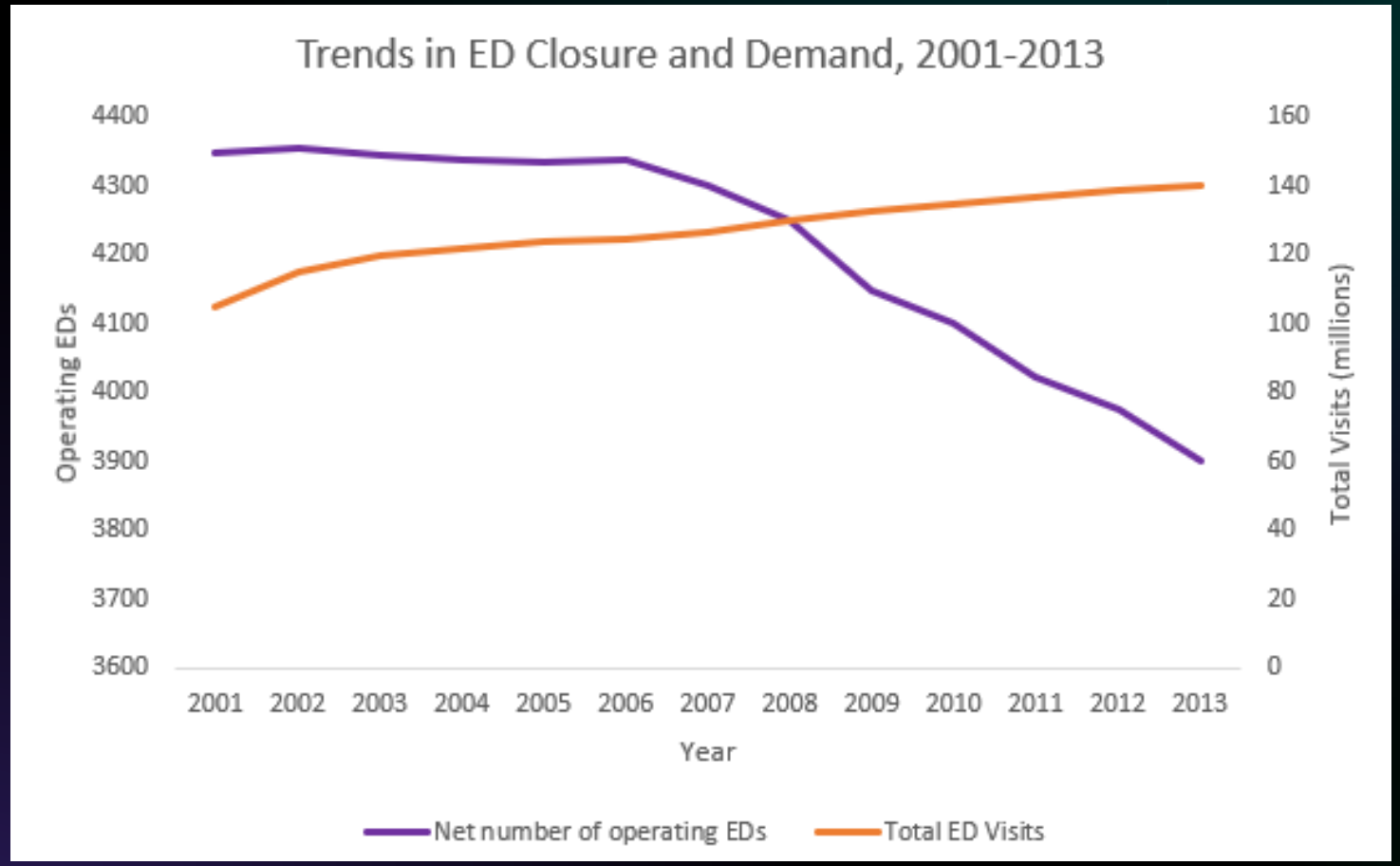
Our medical system faces a crisis of resources.

EDs are a social safety net.





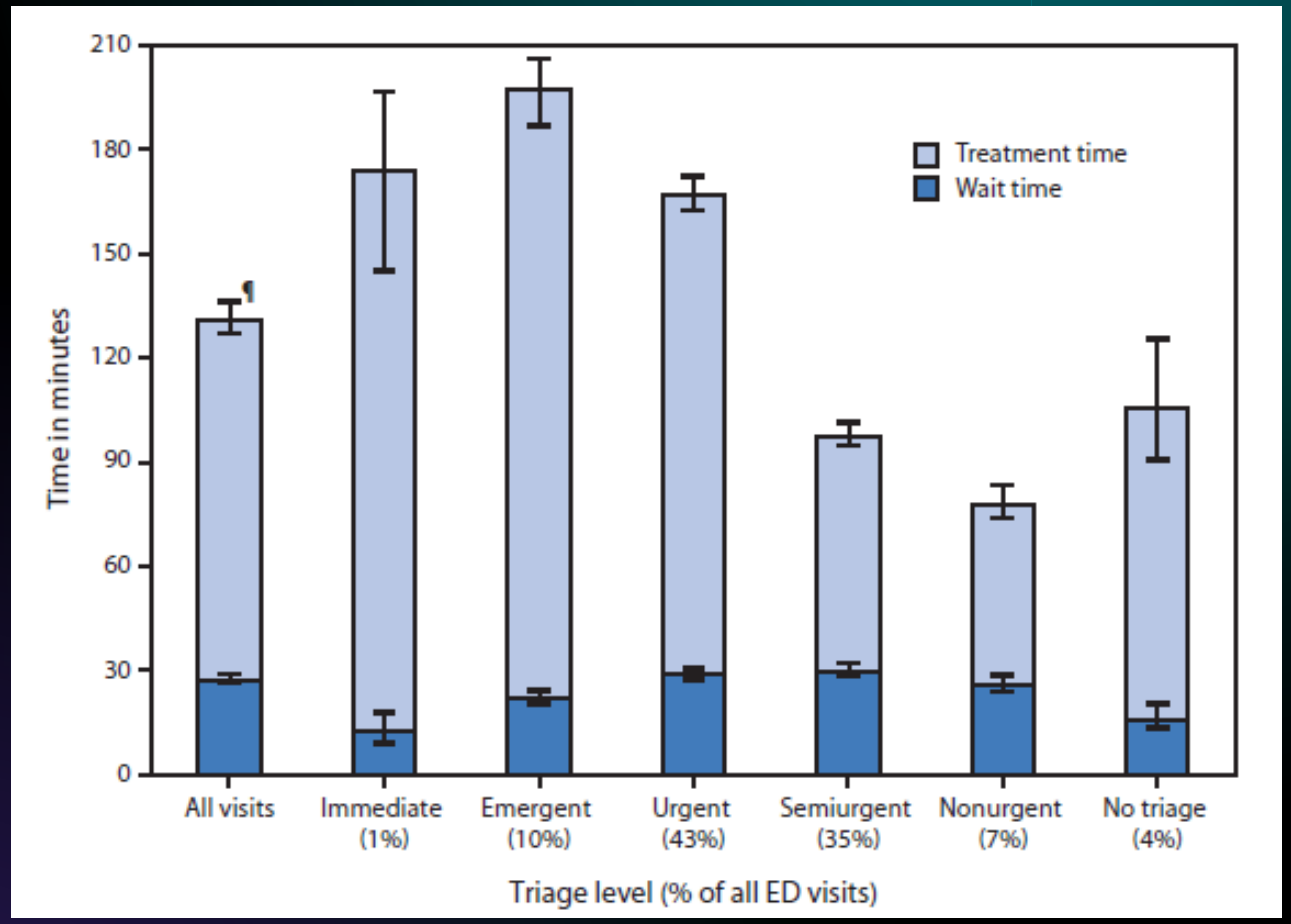
Emergency departments (EDs) face overcrowding and shortages.



Source: Author's analysis of data from AHA and Health Affairs

90% of EDs

- Report overcrowding as a recurrent problem.
- Experience absences or shortages of critical medicine.



Misallocation of resources has deadly consequences.

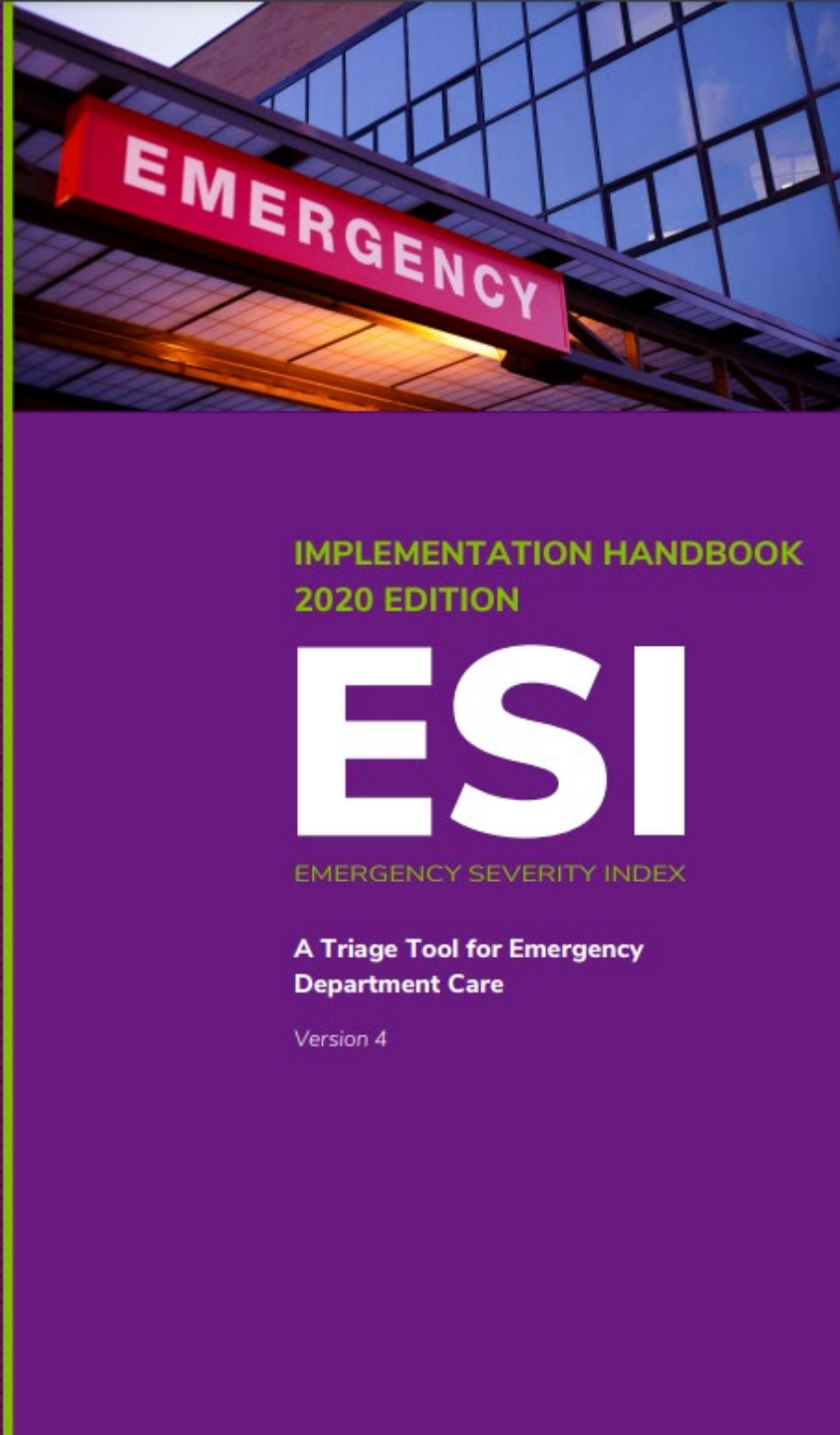
- Delays in care:
  - increase overcrowding.
  - increase demand on EDs.
  - raise overall operating costs.
  - may increase relative risk of mortality by 25%.

Current strategies rely on practitioner subjectivity.

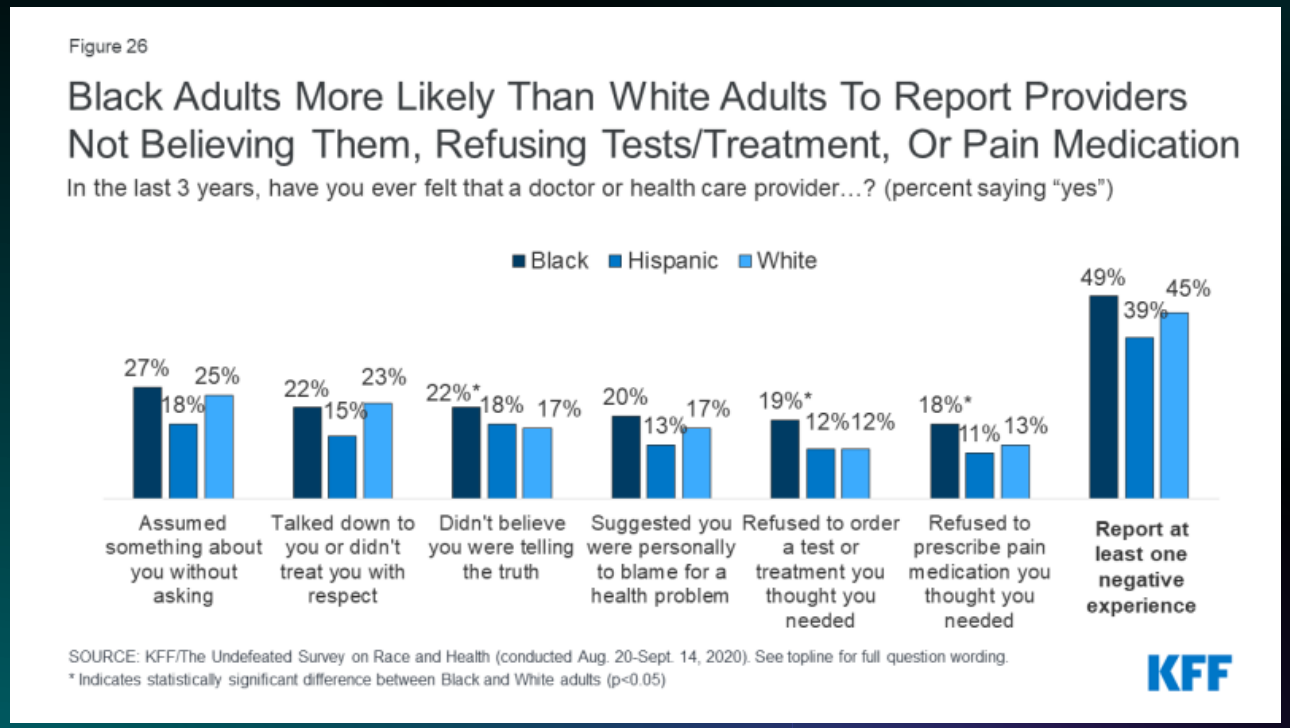
Is This a High-Risk Situation?

Based on a brief patient interview, gross observations, and finally the "sixth sense" that comes from experience, the triage nurse identifies the patient who is high risk. Frequently the patient's age and past medical history influence the triage nurse's determination of risk.

ESI Handbook, page 11



But medicine's long history of bias calls subjectivity into question.



Physicians commonly underassess pain and under-prescribe pain medication for people of color.

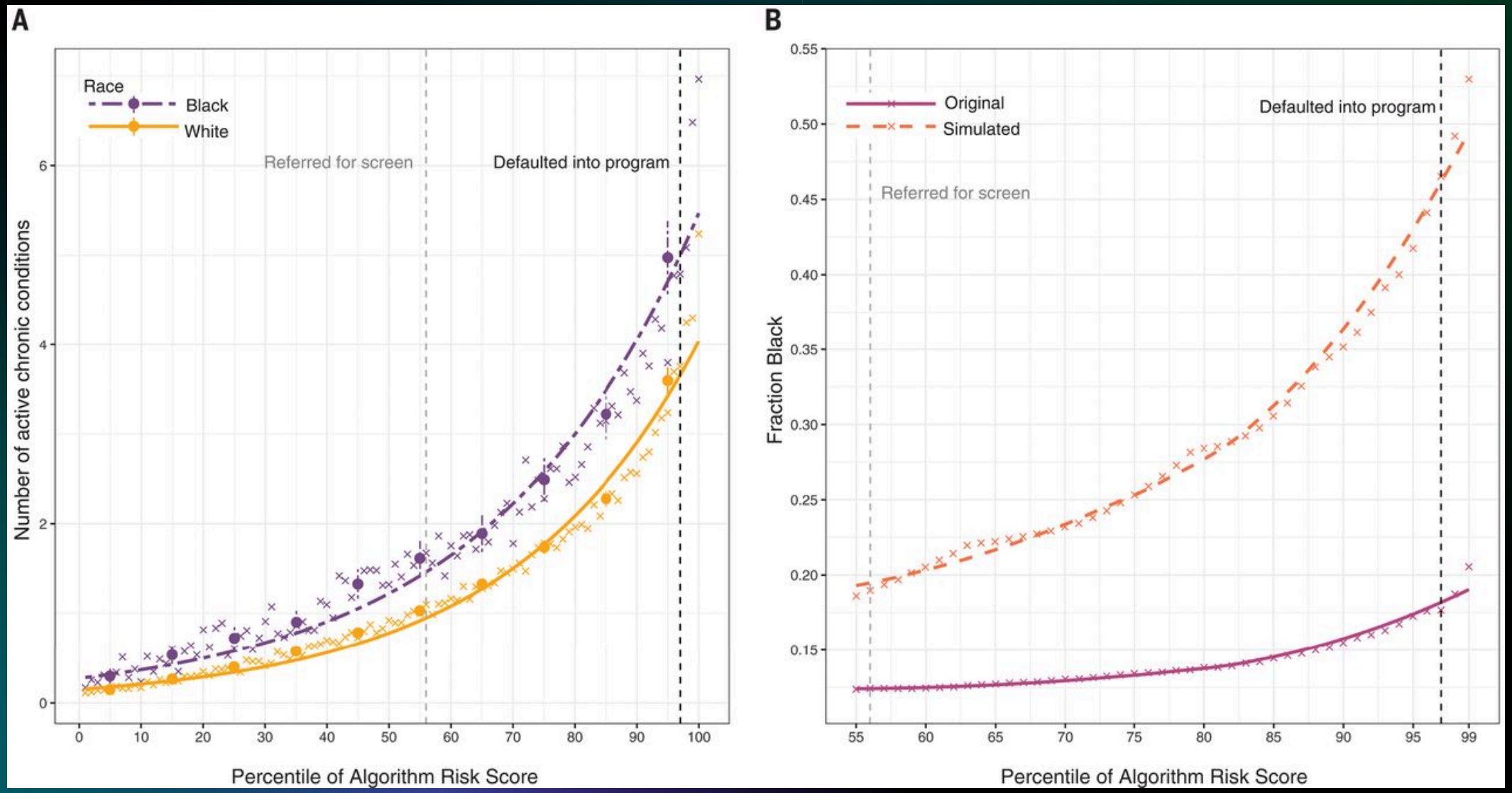
Black patients face longer ED wait times than white patients.

Women are less likely to receive ICU treatment, regardless of illness severity.

Physicians prioritize referrals and wait time targets.

Practitioners suffer from cognitive biases like anchoring, confirmation bias, and diagnostic bias.

Although machine learning may reduce biases, it is certainly not immune to them.



No effective safeguards exist to protect people from discriminatory AI in this domain.

Recommendation 1: Grant the FDA jurisdiction over medical resource allocation systems (MRAS)

FDA's prior work on SAMD makes them an ideal regulatory body.

Breakthrough Devices program and Small Businesses program support developers.

FDA's trade secret practices balance harms of algorithmic disclosure with public safety.

FDA approval may encourage hospital adoption.

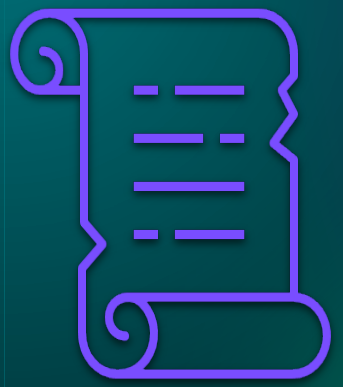
Implementation:

Construe §201(h)(B) of the Federal Food, Drug, and Cosmetic Act

"[a device is] an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is…

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals…"

to include medical risk assessment systems.



Congressional Amendment

Executive Order

Agency Interpretation

Recommendation 2: Identify and endorse standardized MRAS

- Increases hospital buy-in.
- Spurs innovation.
- Enables practitioners to apply their expertise to find a software that works well with their workflow.
- Could lead to trainings and other means to improve adoption.

Recommendation 3: Establish a Federal Artificial Intelligence Bureau

Next Steps

Grant Jurisdiction

Executive Order to grant FDA jurisdiction over medical resource allocation systems as a medical device

Spur Innovation

Ask medical organizations like ENA and ACEP to identify and endorse model systems

Establish an AI Bureau

Congress should establish an AI Bureau with regulatory, enforcement, and advisory powers to guide the future of AI in all domains

Questions?

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