Public-private Partnerships in the Trustworthy Health AI Ecosystem

Michael Pencina, Chief Data Scientist, Duke Health,
Board Secretary, Coalition for Health AI (CHAI)

Brian Anderson, Chief Executive Officer, CHAI

AI at the Center of National Attention

THE WHITE HOUSE

OCTOBER 30, 2023

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

BRIEFING ROOM › STATEMENTS AND RELEASES

Aims to promote the development and use of AI in a manner that is safe, secure, and trustworthy.

Requires reporting to the federal government for any AI model trained on more than 10^{26} Floating Point Operations (100 Septillion)

Directs federal agencies to review their use of AI and develop plans to implement the principles.

Establishes a task force to coordinate federal efforts on AI and to provide recommendations on how to improve the government's use of AI.

Emphasizes the importance of collaboration with the private sector, academia, and civil society to advance the development and use of trustworthy AI.

Regulatory Landscape Changing Rapidly

Contains Nonbinding Recommendations

Clinical Decision Support S

Guidance for Industry
Food and Drug Administrat

Document issued on September 28, 2022

The draft of this document was issued on Septemb

For questions about this document regarding CDRH-regulated devices, c

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Proposed Rule

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

A Proposed Rule by the Health and Human Services Department on 04/18/2023

HHS.gov
Civil Rights

U.S. Department of Health & Human Services

I'm looking for...

A-Z Index

Information for Individuals | Filing a Complaint | Information for Providers | Newsroom

HHS > Civil Rights Home > For Providers > For Providers of Health Care & Social Services > Regulatory Initiatives > Fact Sheet: Nondiscrimination in Health Programs and Activities Proposed Rule Section 1557 of the Affordable Care Act

Civil Rights for Providers of
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t Examples

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Fact Sheet: Nondiscrimination in Health Programs and Activities Proposed Rule Section 1557 of the Affordable Care Act

The Department of Health and Human Services (HHS) has issued a proposed rule to advance health equity and reduce disparities in health care. The proposed rule, *Nondiscrimination in Health Programs and Activities*, revises the implementing regulation for Section 1557 of the Affordable Care Act (ACA), and proposes robust provisions that will be more effective in protecting people from discrimination.

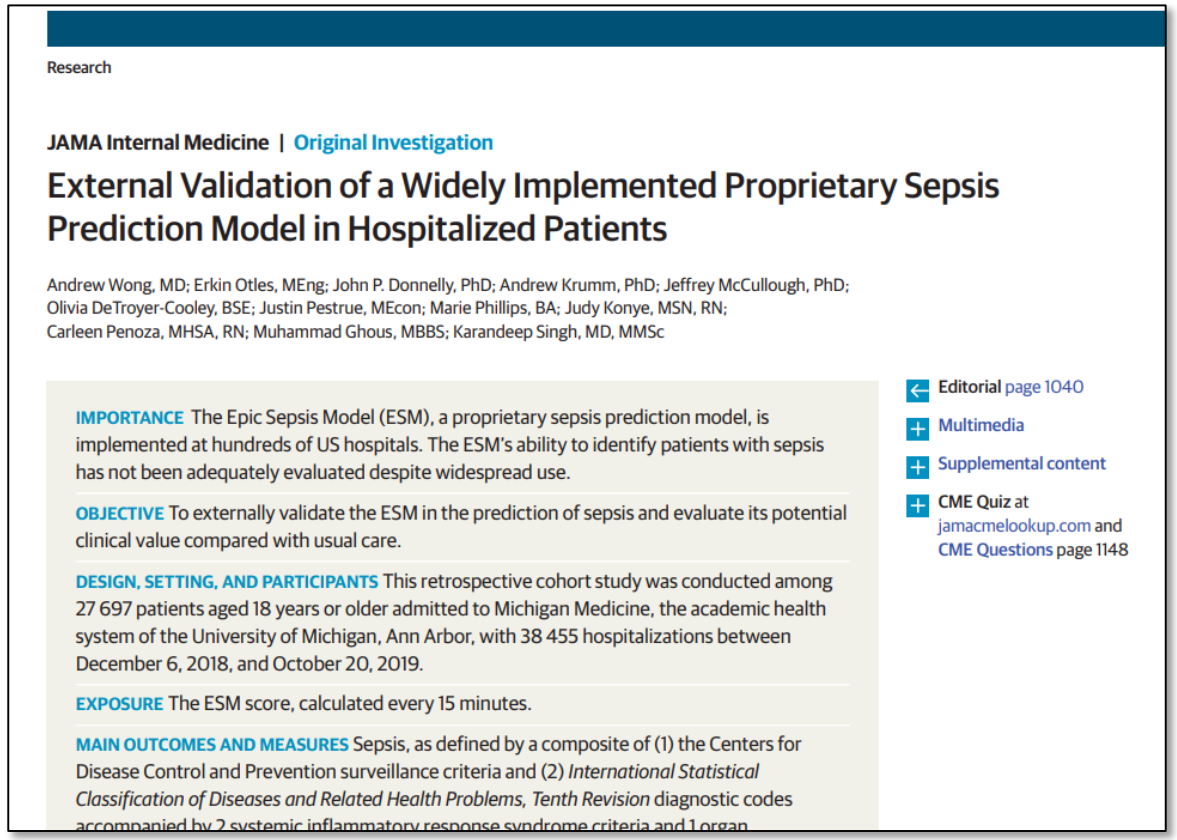
Section 1557 of the ACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs or activities and is one of the government's most powerful tools to ensure nondiscriminatory access to health care. In addition to proposing revisions to the Section 1557 implementing regulation, this rulemaking also includes proposed revisions to nondiscrimination

“Wild West” of Algorithms

“We have a Wild West of algorithms,” said Michael Pencina, coalition [CHAI] co-founder and director of Duke AI Health. There’s so much focus on development and technological progress and not enough attention to its value, quality, ethical principles or health equity implications.”

Politico, April 4, 2023

AI/ML Risks



Research

JAMA Internal Medicine | Original Investigation

External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients

Andrew Wong, MD; Erkin Otles, MEng; John P. Donnelly, PhD; Andrew Krumm, PhD; Jeffrey McCullough, PhD; Olivia DeTroyer-Cooley, BSE; Justin Pestrue, MEcon; Marie Phillips, BA; Judy Konye, MSN, RN; Carleen Penoza, MHSA, RN; Muhammad Ghous, MBBS; Karandeep Singh, MD, MMSc

IMPORTANCE The Epic Sepsis Model (ESM), a proprietary sepsis prediction model, is implemented at hundreds of US hospitals. The ESM's ability to identify patients with sepsis has not been adequately evaluated despite widespread use.

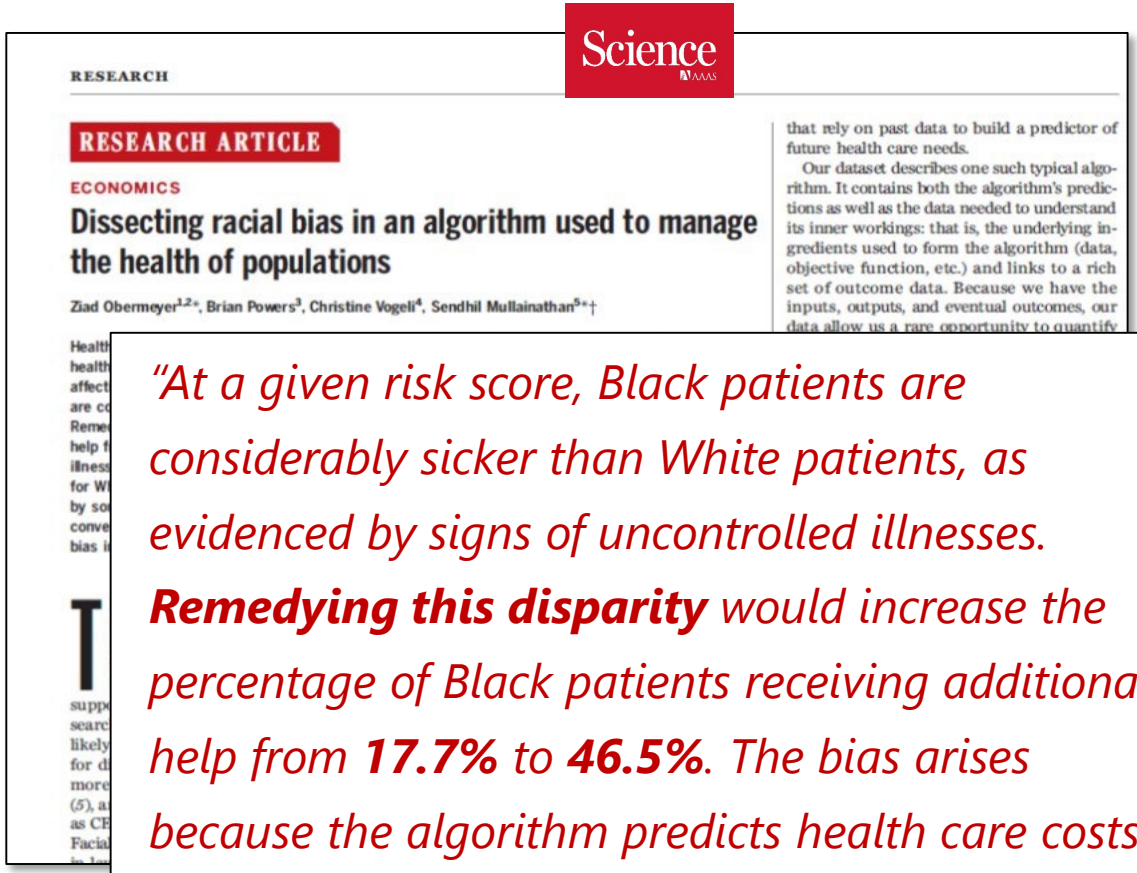
OBJECTIVE To externally validate the ESM in the prediction of sepsis and evaluate its potential clinical value compared with usual care.

DESIGN, SETTING, AND PARTICIPANTS This retrospective cohort study was conducted among 27 697 patients aged 18 years or older admitted to Michigan Medicine, the academic health system of the University of Michigan, Ann Arbor, with 38 455 hospitalizations between December 6, 2018, and October 20, 2019.

EXPOSURE The ESM score, calculated every 15 minutes.

MAIN OUTCOMES AND MEASURES Sepsis, as defined by a composite of (1) the Centers for Disease Control and Prevention surveillance criteria and (2) *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* diagnostic codes accompanied by 2 systemic inflammatory response syndrome criteria and 1 organ

Editorial page 1040
Multimedia
Supplemental content
CME Quiz at jamacmelookup.com and CME Questions page 1148



Science AAAS

RESEARCH

RESEARCH ARTICLE

ECONOMICS

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

Ziad Obermeyer[1,2]*, Brian Powers[3], Christine Vogeli[4], Sendhil Mullainathan[5]*†

that rely on past data to build a predictor of future health care needs.

Our dataset describes one such typical algorithm. It contains both the algorithm's predictions as well as the data needed to understand its inner workings: that is, the underlying ingredients used to form the algorithm (data, objective function, etc.) and links to a rich set of outcome data. Because we have the inputs, outputs, and eventual outcomes, our data allow us a rare opportunity to quantify

"At a given risk score, Black patients are considerably sicker than White patients, as evidenced by signs of uncontrolled illnesses. ***Remedying this disparity*** *would increase the percentage of Black patients receiving additional help from* ***17.7%*** *to* ***46.5%****. The bias arises because the algorithm predicts health care costs rather than illness..."*

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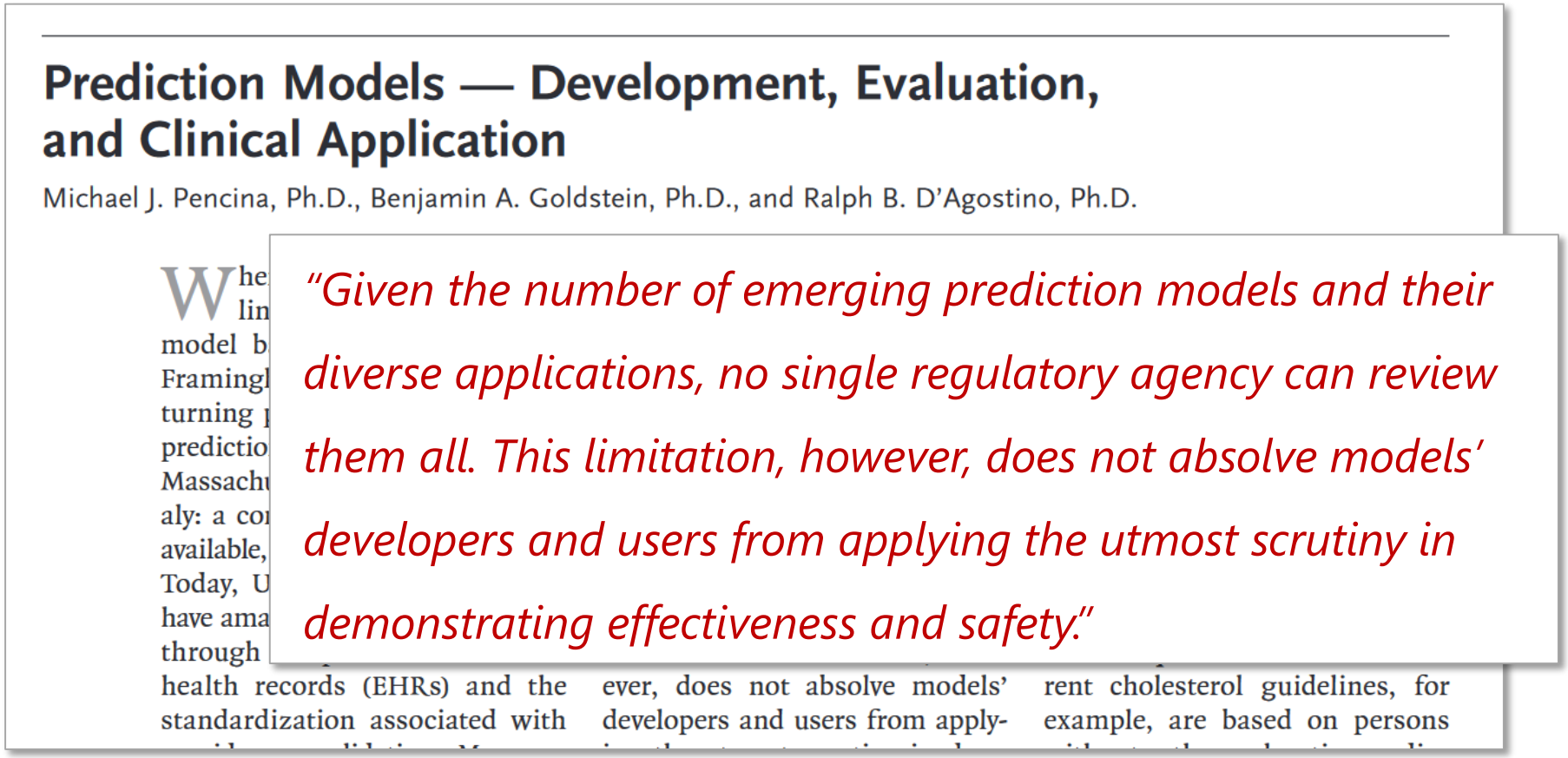
We need to do better



Prediction Models — Development, Evaluation, and Clinical Application

Michael J. Pencina, Ph.D., Benjamin A. Goldstein, Ph.D., and Ralph B. D'Agostino, Ph.D.

"Given the number of emerging prediction models and their diverse applications, no single regulatory agency can review them all. This limitation, however, does not absolve models' developers and users from applying the utmost scrutiny in demonstrating effectiveness and safety."

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Pencina MJ, Goldstein BA, D'Agostino RB. *N Engl J Med*. 2020 Apr 23;382(17):1583-1586. doi: 10.1056/NEJMp2000589.

Principles for Responsible AI

- Ensure that AI technology serves humans
- Define the task we want the AI tool to accomplish
- Describe what the successful use of the AI tool looks like
- Create transparent systems for continuously testing and monitoring AI tools

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ABCDS Oversight Mission Statement

"Out of our primary focus on patient safety and high-quality care, our mission is to guide algorithm-based clinical decision support (ABCDS) tools through their lifecycle by providing governance, evaluation, and monitoring."

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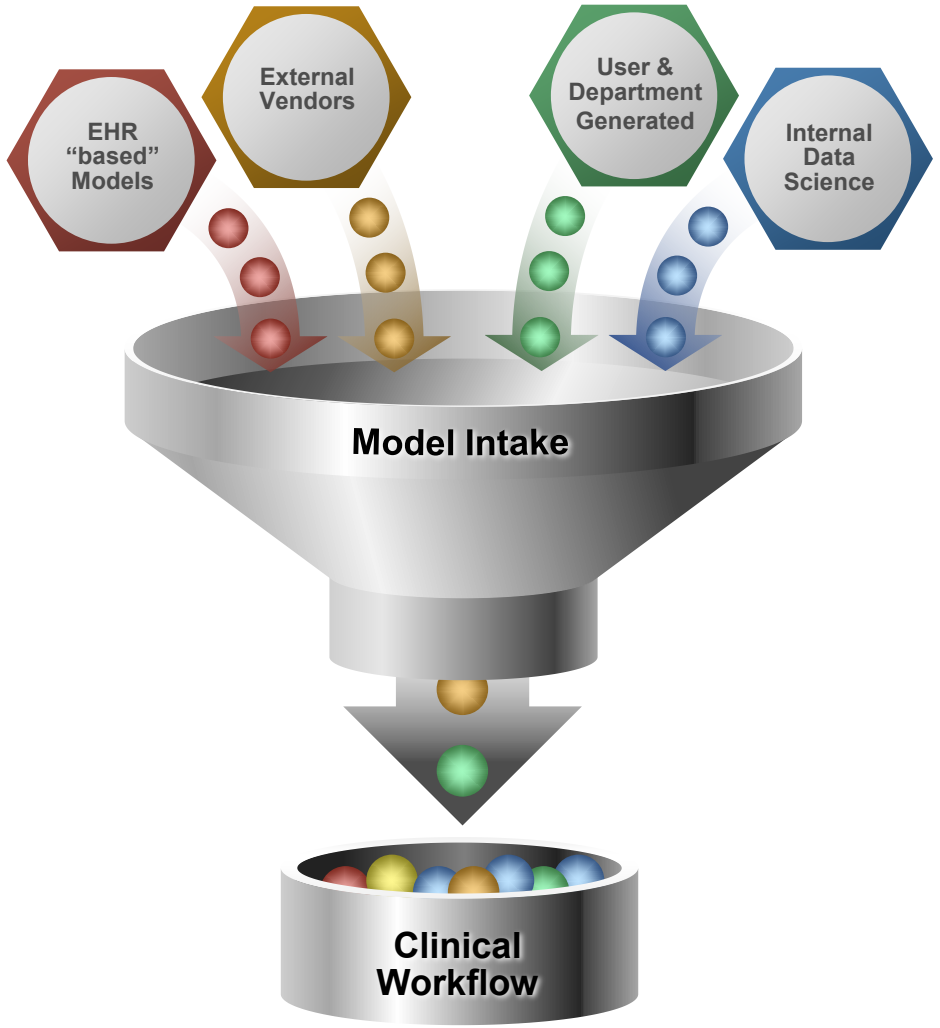
Complex Environment

Different:

- Skills
- Knowledge bases
- Resources available
- Make up of project teams



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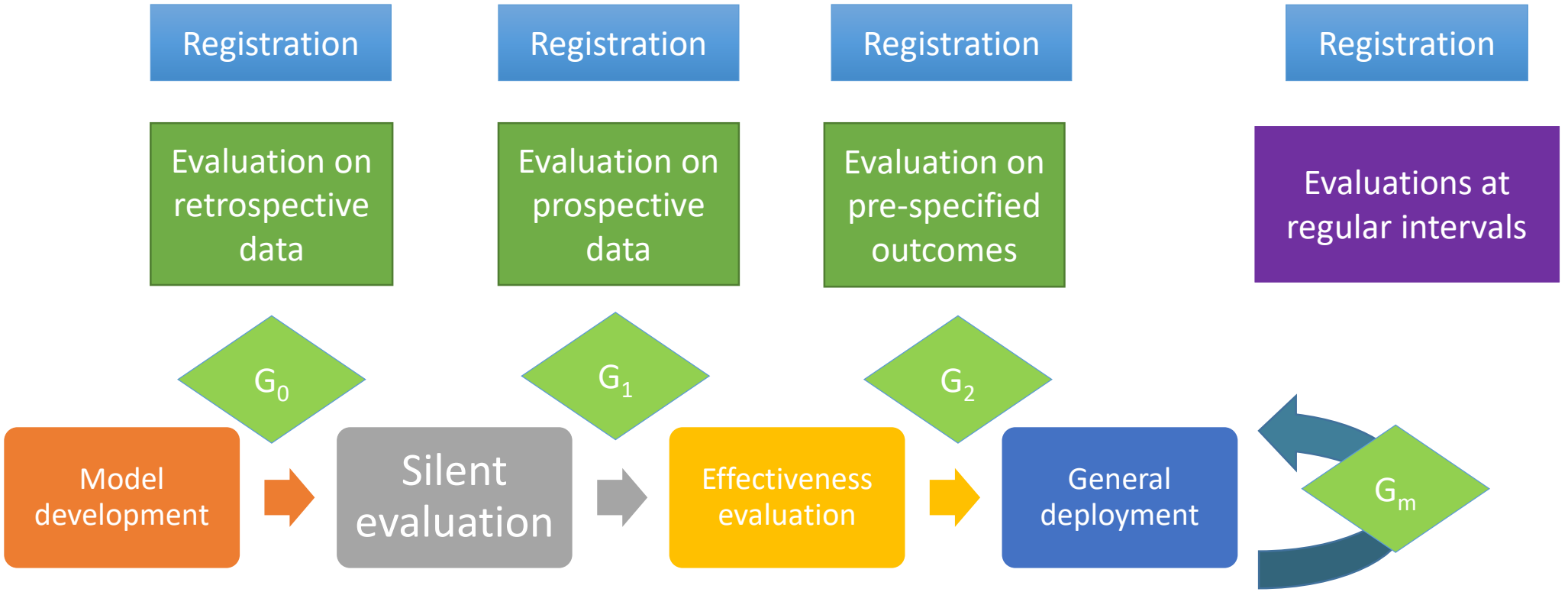
Evaluations Across Algorithm Lifecycle



Bedoya et al., JAMIA. 2022; 1-6, https://doi.org/10.1093/jamia/ocac078

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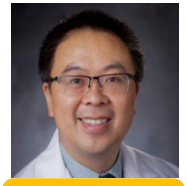
People: ABCDS Oversight Committee

Co-Chairs:


M Pencina


E Poon

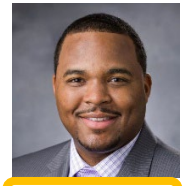
Director:


N Economou

ABCDS Oversight Committee

Additional Committee Members:


S Balu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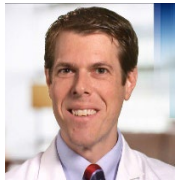
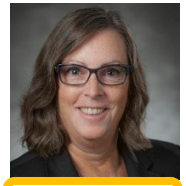
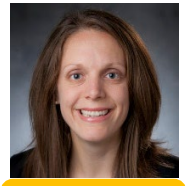

M Lipkin


K Lytle

ABCDS Regulatory Advisory Subcommittee

Co-Chairs:


A Parrish

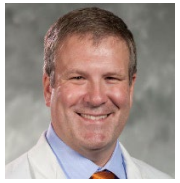

S Elengold

S Ellison

ABCDS Evaluation Subcommittee

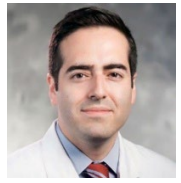
Co-Chairs:

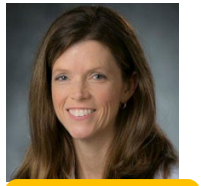

B Goldstein


E Jelovsek

ABCDS Implementation and Monitoring Subcommittee

Co-Chairs:


A Bedoya


C O'Brien

Ops Team::


S Bessias


N Walden

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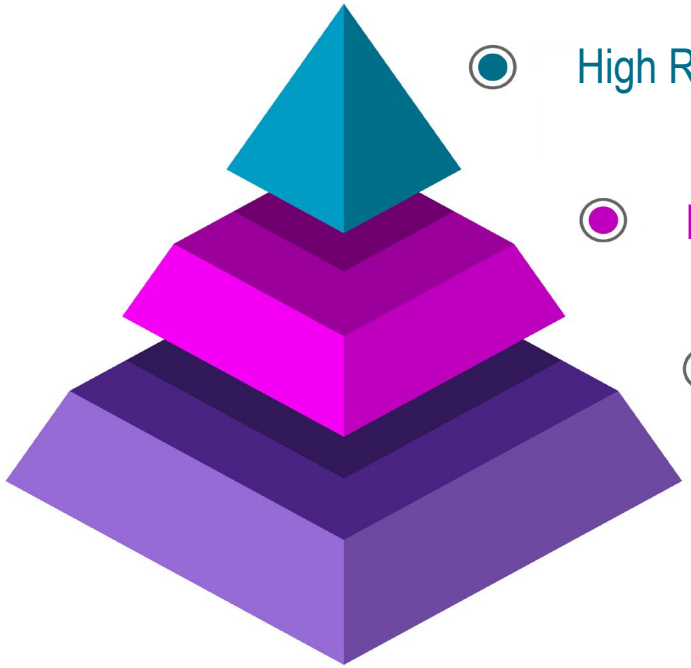
Scope of ABCDS Oversight Framework

ABCDS Tool = Algorithm(s) + Interface Algorithms Are Presented In

All electronic algorithms that could impact patient care at Duke Health fall within the scope of the ABCDS Oversight Committee and must undergo registration.



- High Risk: Data-Derived
- Medium Risk (e.g., Clinical Consensus)
- Low Risk: Standard of Care

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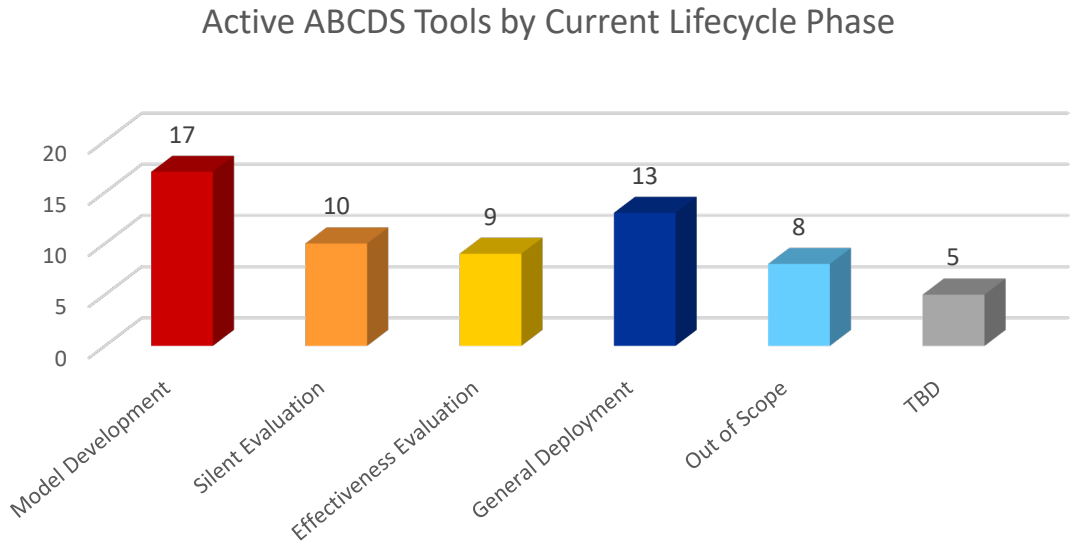
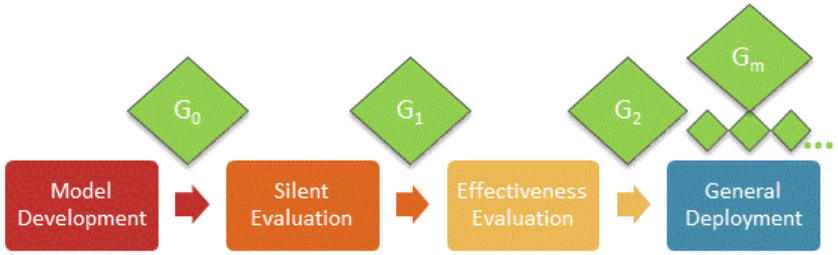
Duke ABCDS Oversight Portfolio Metrics

ABCDS Model Registration and Review	Total
Number of active tools* (includes unregistered)	62
Number of active tools registered	43
Number of active tools evaluated	28

** Tools currently in use or proposed for use at DUHS (excluding retired, on hold)*





Current Focus Areas

MLOps Operational Unit

Evaluation of Generative AI

Expanding into Imaging AI

Assessment of value of AI tools

National Health AI Pledge

ANALYTICS IN ACTION NEWS

DukeHealth

Mass General Brigham

EMORY HEALTHCARE

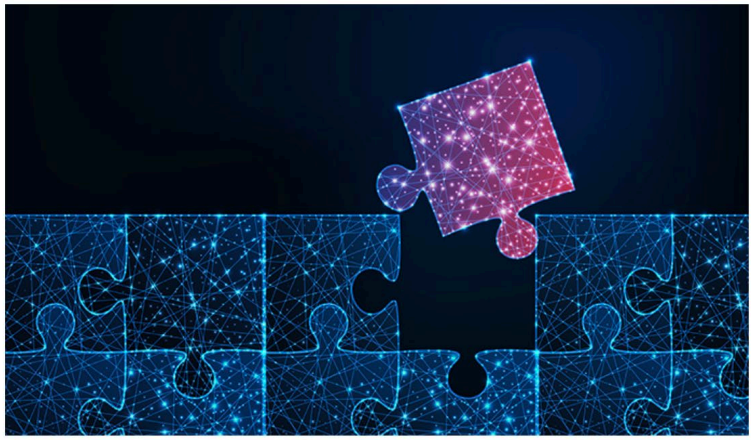
MUSC Health
MEDICAL UNIVERSITY of SOUTH CAROLINA

UC San Diego
HEALTH SYSTEM

+20 Others

Providers, Payers Sign Pledge for Ethical, Responsible AI in Healthcare

Over 25 health systems and payers have made voluntary commitments to ensure that health AI leads to fair, appropriate, valid, effective, and safe outcomes.



Source: Getty Images

By Shania Kennedy

1. We commit to vigorously developing AI solutions to optimize healthcare delivery and payment by advancing health equity, expanding access, making healthcare more affordable, improving outcomes through more coordinated care, improving patient experience, and reducing clinician burnout.

2. We will work with our peers and partners to ensure outcomes are aligned with fair, appropriate, valid, effective, and safe (FAVES) AI principles.

3. We will deploy trust mechanisms that inform users if content is largely AI-generated and not reviewed or edited by a human.

4. We will adhere to a risk management framework that includes comprehensive tracking of applications powered by frontier models and an accounting for potential harms and steps to mitigate them.

5. We will research, investigate, and develop swiftly but will do so responsibly.

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Who We Are

- Over **1300+ Private Sector Organizations:** Health Systems, Payors, Device Manufacturers, Technology Companies, Patient Advocates
- **US Govt Partners:** HHS, FDA, ONC, NIH, CMS, White House OSTP, AHRQ, VA, NIST, **CDC, OCR**
- Formally became **501c6 non-profit** in Jan 2024

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Vision & Mission Statement

Our Vision is to be the trusted source for Responsible Health AI that serves all of us.

Our Mission is to provide a framework for the landscape of health AI tools to ensure high quality care, increase trust amongst users, and meet health care needs.

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Over 1300 private sector organization members

Including Health Systems, Payors, Device Manufacturers, Technology Companies, Patient Advocates

Founding Members

- Mayo Clinic
- DukeHealth
- MITRE
- Berkeley University of California
- Johns Hopkins University
- Stanford Medicine
- UCSF University of California San Francisco

Industry Partners

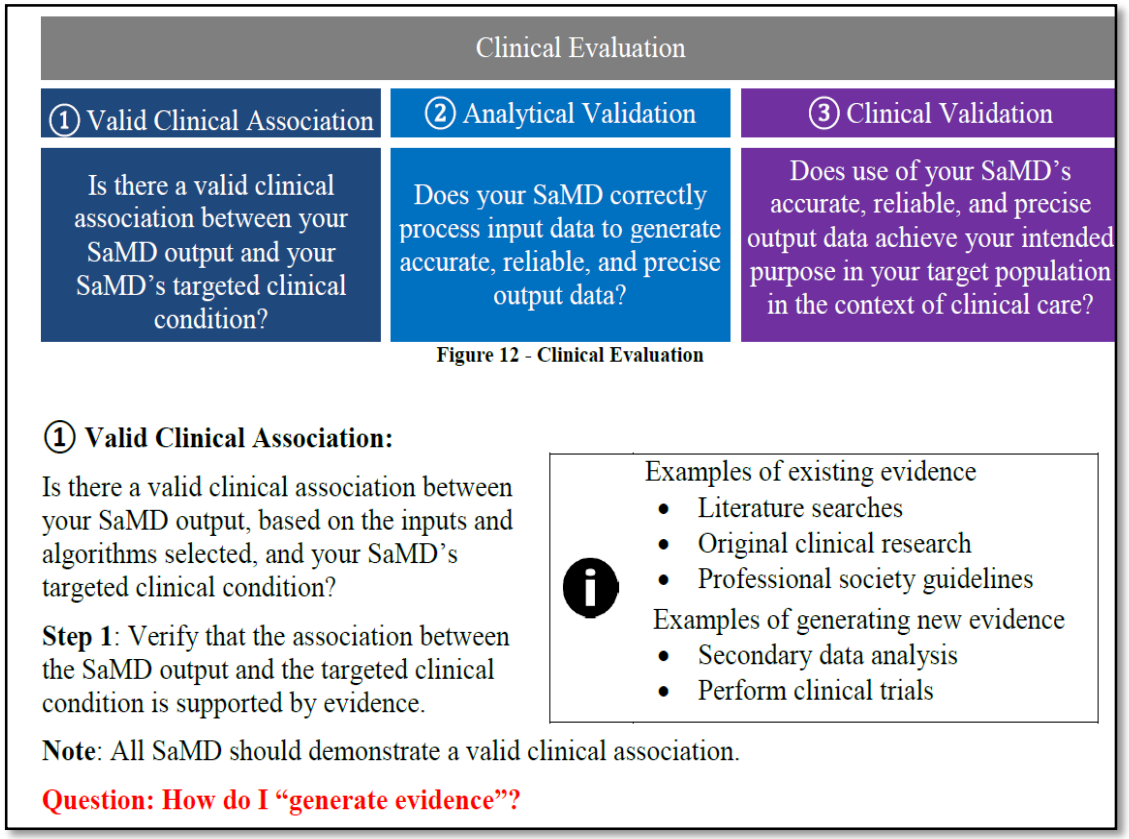
- Change Healthcare Part of Optum
- SAS
- Google
- Microsoft

US Government Partners

- FDA
- ONC Office of the National Coordinator for Health Information Technology
- NIH National Institutes of Health
- Office of Science and Technology Policy
- AHRQ
- CMS Centers for Medicare & Medicaid Services
- VA
- NIST National Institute of Standards and Technology U.S. Department of Commerce

Implementation Guide Inspiration

- FDA's Software as a Medical Device Clinical Evaluation (2017)
  - https://www.fda.gov/media/100714/download
- Health IT.gov Argonaut Project for FHIR
  - https://www.fhir.org/guides/argonaut/
  - https://www.healthit.gov/isa/collection-and-exchange-patient-reported-outcomes



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BLUEPRINT FOR TRUSTWORTHY AI IMPLEMENTATION GUIDANCE AND ASSURANCE FOR HEALTHCARE

COALITION FOR HEALTH AI

VERSION 1.0 _ APRIL 04, 2023

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Core Principles of Trustworthy AI

- Valid
- Beneficial & Effective
- Testable
- Reliable & Robust
- Usable

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https://www.coalitionforhealthai.org/papers/blueprint-for-trustworthy-ai_V1.0.pdf

CHAI Work

Aligned to NAM Code of Conduct

AS Guide

AS Reporting Checklist

Privacy & Security Work Group	Fairness Work Group	Transparency Work Group	Usefulness Work Group	Safety Work Group
- Privacy-Enhanced - Secure	- Fair w/ harmful bias managed - Systemic - Computational - Statistical - Human-cognitive	- Accountable - Transparent - Explainable - Interpretable	- Valid for accuracy, operability & meeting its intended purpose and benefit (clinical validation) - Testable - Reliable - Usable - Robust/Generalizable	- Safety

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CHAI Community

Future Focus Areas

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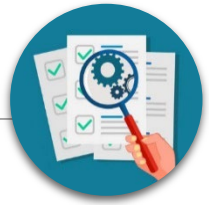
Public-Private Partnership

NATIONAL ACADEMY of MEDICINE



Standards and Tools Assurance Guide
Technical Implementation Guide
Extended scope and best practices for pharma, devices and payers

Safety Surveillance and Monitoring

Nationwide Registry and Educational Content
Catalog of transparency information

Maturity Model
Health System's AI Readiness

Network of Quality Assurance Labs
Democratizing implementation

Large Language Models (LLMs) and Other Use Cases

CHAI
Coalition for Health AI

2024 Work Groups

- Standards & Guidelines (Predictive and Generative)
- Testing & Evaluation Framework (Predictive and Generative)
- Sector Specific Guidance (Payor, CDS, Administrative Management, Life Science, Med Device, Direct to Consumer, Public Health)

Health AI Quality Assurance Labs

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A Federated Network of Labs - All Models are Local

AI Quality Assurance Labs

The Challenge between External vs Local Evaluations

Health AI Developers & Implementer Preparedness for Deployment of Health AI tools

Governance, independent evaluation, anti-bias policies, etc.

Health AI Tool Preparedness for Transparency and Responsible AI practices

Model cards, health data sheets, documentation, registration, etc.

Evaluation Sandbox to Assess Tool Robustness & Performance

Data sharing platform, model report cards, monitoring dashboards

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An Urgent Need to Rethink How We Regulate & Align GenAI
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Thank you