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

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

October 30, 2023

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

Clinical Decision Support System
Guidance for Industry
Food and Drug Administration

Document issued on September 28, 2022

The draft of this document was issued on September 28, 2022.

For questions about this document regarding CDER-regulated devices, contact...(Redacted)

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, the rulemaking also includes proposed revisions to nondiscrimination.

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
“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*
"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..."
“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.”
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
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.”
Complex Environment

Different:

• Skills
• Knowledge bases
• Resources available
• Make up of project teams
Evaluations Across Algorithm Lifecycle

- **Model development** → **Silent evaluation** → **Effectiveness evaluation** → **General deployment** → **Evaluations at regular intervals**

- **G₀**: Evaluation on retrospective data
- **G₁**: Evaluation on prospective data
- **G₂**: Evaluation on pre-specified outcomes

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

Co-Chairs:
- M Pencina
- E Poon

Director:
- N Economou

ABCDS Oversight Committee

Additional Committee Members:
- S Balu
- M Cary
- 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

CHAI™

DukeHealth
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
Duke ABCDS Oversight Portfolio Metrics

**ABCDS Model Registration and Review**

<table>
<thead>
<tr>
<th>Number of active tools* (includes unregistered)</th>
<th>62</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of active tools registered</td>
<td>43</td>
</tr>
<tr>
<td>Number of active tools evaluated</td>
<td>28</td>
</tr>
</tbody>
</table>

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

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Active ABCDS Tools by Current Lifecycle Phase

- Model Development: 17 tools
- Silent Evaluation: 10 tools
- Effectiveness Evaluation: 9 tools
- General Deployment: 13 tools
- Out of Scope: 8 tools
- TBD: 5 tools
Current Focus Areas

- MLOps Operational Unit
- Evaluation of Generative AI
- Expanding into Imaging AI
- Assessment of value of AI tools
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.
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
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.
Over 1300 private sector organization members
Including Health Systems, Payors, Device Manufacturers, Technology Companies, Patient Advocates

Founding Members

Duke Health
MITRE

Industry Partners

CHANGE HEALTHCARE
Part of Optum

Sas
Google
Microsoft

US Government Partners

FDA
ONC
NIH
FDA
Office of the National Coordinator for Health Information Technology

National Institutes of Health
Office of Science and Technology Policy
AHRQ
CMS
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/
BLUEPRINT FOR TRUSTWORTHY AI IMPLEMENTATION GUIDANCE AND ASSURANCE FOR HEALTHCARE

COALITION FOR HEALTH AI

Version 1.0 _ April 04, 2023
Core Principles of Trustworthy AI

- Valid
- Beneficial & Effective
- Testable
- Reliable & Robust
- Usable
- Privacy, Security & Resilience
- Explainability & Interpretability
- Accountability & Transparency
- Safety
- Usefulness
- Fairness & Equity

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
- Privacy-Enhanced
- Secure

Fairness Work Group
- Fair w/ harmful bias managed
- Systemic
- Computational
- Statistical
- Human-cognitive

Transparency Work Group
- Accountable
- Transparent
- Explainable
- Interpretable

Usefulness Work Group
- Valid for accuracy, operability & meeting its intended purpose and benefit (clinical validation)
- Testable
- Reliable
- Usable
- Robust/Generalizable

Safety Work Group
- Safety

Privacy & Security
Fairness
Transparency
Usefulness
Safety

Aligned to NAM Code of Conduct

Safety Work Group

Fairness Work Group

Privacy & Security Work Group

Usefulness Work Group

CHAI Work

CHAI Community

CHAI™
Future Focus Areas

Public-Private Partnership

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