NUTRITION FACTS LABELS FOR AI/ML TRANSPARENCY AND TRUST

FDA Virtual Public Workshop - Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices

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Presenter: Barbara Barry, PhD
Collaborative Scientist, Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery / Assistant Professor of Medicine, Division of Health Care Delivery Research, Mayo Clinic
Contact: barry.barbara@mayo.edu
DEFINITION OF ARTIFICIAL INTELLIGENCE (AI)

“Artificial Intelligence (AI) is a science and a set of computational technologies that are inspired by—but typically operate quite differently from—the ways people use their nervous systems and bodies to sense, learn, reason, and take action.”

## CONNECTING SCIENCE AND TOOL

<table>
<thead>
<tr>
<th>Science</th>
<th>Technological tool</th>
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</thead>
<tbody>
<tr>
<td>Can we do it?</td>
<td>Should we use it?</td>
</tr>
<tr>
<td>Is it possible?</td>
<td>How should it be used?</td>
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<tr>
<td>Can a computer sense, learn, reason, or take action in a particular way that is inspired by people?</td>
<td>How should this tool for sensing, reasoning, or taking action be used and what are the consequences?</td>
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PROMISE OF MACHINE LEARNING IN MEDICINE

New AI/ML tools show promise to support providers and patients in variety of ways

- Prognosis
- Diagnosis
- Treatment
- Workflow
- Efficiency
- Access

PATIENT HOPES AND CONCERNS FOR MEDICAL AI

Preservation of patient choice and autonomy

I think it all comes back to choice, though, I think everybody’s getting the mentality that, and maybe I’m wrong, but that an AI is being pushed, but at the end of the day, our choice is still our choice, and it’s not being taken away. (FG 15).

~ Patient quote from focus group

PRINCIPLES OF TRUSTWORTHY AI:
ONE MODEL OF MANY

Data-driven research framework for TAI (DaRe4TAI)

• Beneficence
• Non-maleficence
• Autonomy
• Justice
• Explicability

NUTRITION FACTS LABELS FOR TRANSPARENCY

https://donaskitchen.com/best-frozen-lasagna/

INFORMATION TO MAKE DECISIONS

AI/ML “NUTRITION” LABELS FROM RESEARCH


YALE-MAYO CERSI COLLABORATION WITH FDA DIGITAL HEALTH CENTER FOR EXCELLENCE

**Title:** Patient and provider informed labeling of AI/ML-Based Software to enable transparency and trust for cardiac monitoring and diagnostics

**Goal:** Specify the core labeling ingredients for AI/ML-based cardiac software and medical devices

**Objective:** Collect data representing a broad range of needs and attitudes from patients and providers to enable trustworthy and transparent labeling of AI/ML-based cardiac software and devices
WHAT DO YOU THINK?

Would you want to know if AI is being used in your medical care?

What information would you want to know about the AI used in your medical care?

What level of physician oversight is needed for medical AI?

What would make an AI tool used in medicine trustworthy?
THANK YOU!

Barbara Barry, PhD – PI, Mayo Clinic
Jennifer Miller, PhD – Co-PI, Yale
Joseph Ross, MD PhD, Co-PI, Yale
Jennifer Ridgeway, PhD – Co-PI, Mayo Clinic

Xuan Zhu, PhD, Analyst, Mayo Clinic
Austin Stroud, MA, Study Coordinator, Mayo Clinic

Peter Noseworthy, MD, Advisor, Mayo Clinic
Richard Sharp, PhD, Advisor, Mayo Clinic

Lindsay Emanuel, Program Manager, Mayo Clinic
Jessica Ritchie, Program Manager, Yale

Molly Jeffery, PhD, Mayo CERSI Partnership Lead
Joseph Ross, MD PhD, Yale CERSI Partnership Lead