

# 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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# 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

Science

Technological tool

**Can we do it?**

**Is it possible?**

Can a computer sense, learn, reason, or take action in a particular way that is inspired by people?

**Should we use it?**

**How should it be used?**

How should this tool for sensing, reasoning, or taking action be used and what are the consequences?

Stanford Report: "AI and Life in 2030: 100-year study of AI" (2015)

# 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

Rajkomar, A., Dean, J., & Kohane, I. (2019). Machine learning in medicine. *New England Journal of Medicine*, 380(14), 1347-1358.

# 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).*

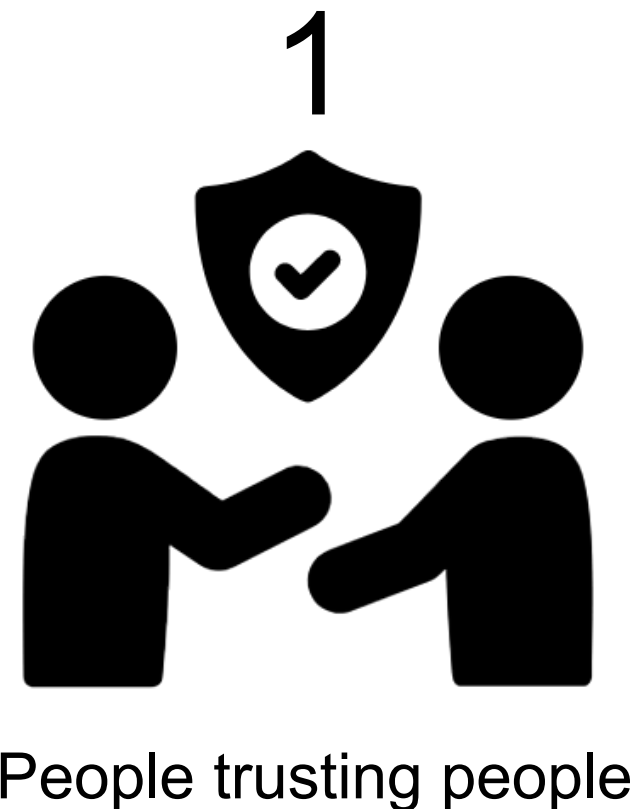
~ Patient quote from focus group

Richardson, J. P., Smith, C., Curtis, S., Watson, S., Zhu, X., Barry, B., & Sharp, R. R. (2021). Patient apprehensions about the use of artificial intelligence in healthcare. *npj Digital Medicine*, 4(1), 140. doi:10.1038/s41746-021-00509-1

# 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/>

1. Serving Information →

2. Calories →

3. Nutrients →

4. Quick Guide to percent Daily Value (%DV) ←

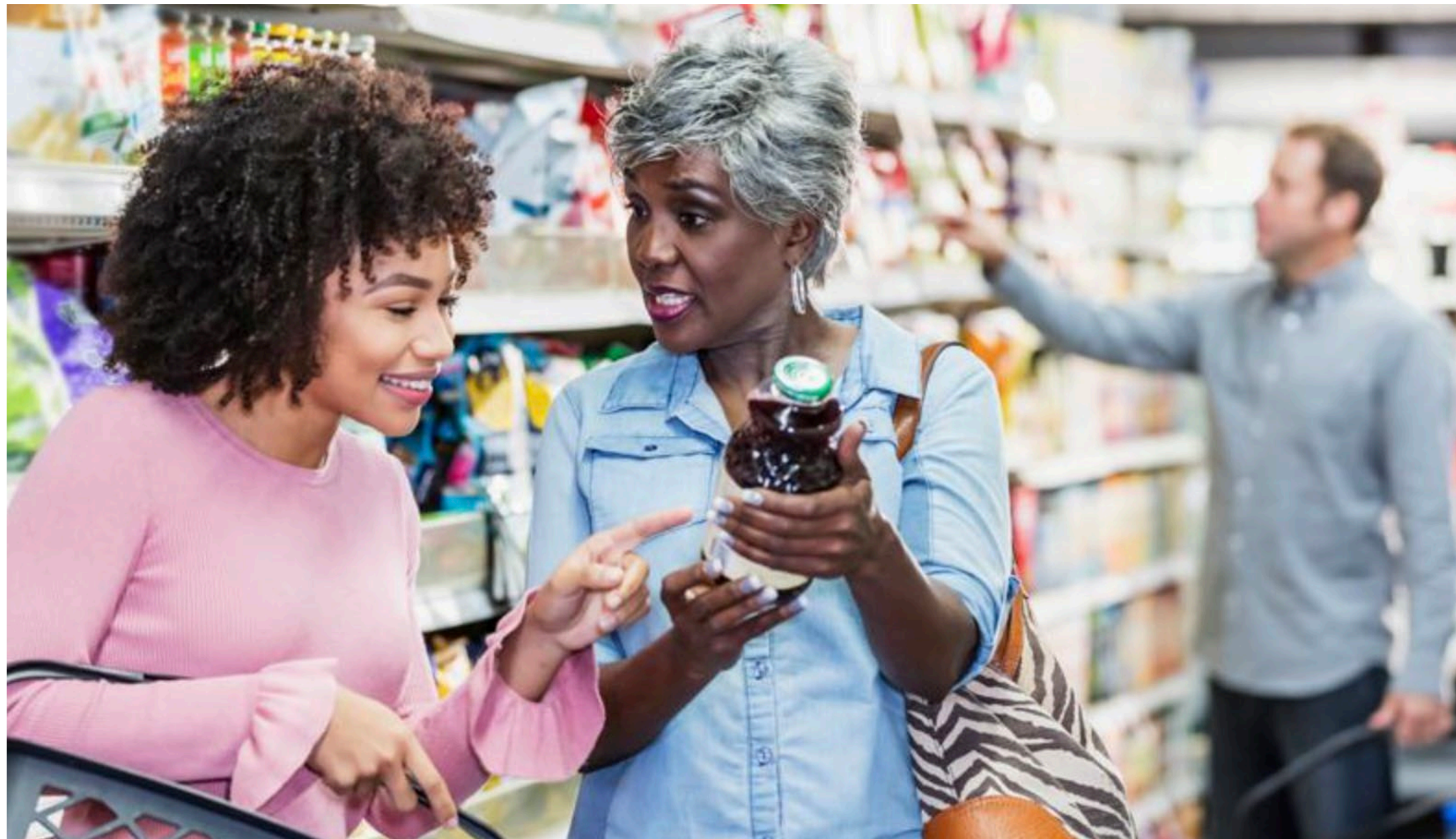
- 5% or less is **low**
- 20% or more is **high**

<b>Nutrition Facts</b>	
4 servings per container	
<b>Serving size</b>	<b>1 cup (227g)</b>
<b>Amount per serving</b>	
<b>Calories</b>	<b>280</b>
	<b>% Daily Value*</b>
<b>Total Fat</b> 9g	<b>12%</b>
Saturated Fat 4.5g	<b>23%</b>
Trans Fat 0g	
<b>Cholesterol</b> 35mg	<b>12%</b>
<b>Sodium</b> 850mg	<b>37%</b>
<b>Total Carbohydrate</b> 34g	<b>12%</b>
Dietary Fiber 4g	<b>14%</b>
Total Sugars 6g	
Includes 0g Added Sugars	<b>0%</b>
<b>Protein</b> 15g	
Vitamin D 0mcg	0%
Calcium 320mg	25%
Iron 1.6mg	8%
Potassium 510mg	10%

\* The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

<https://www.fda.gov/food/new-nutrition-facts-label/how-understand-and-use-nutrition-facts-label>

# INFORMATION TO MAKE DECISIONS


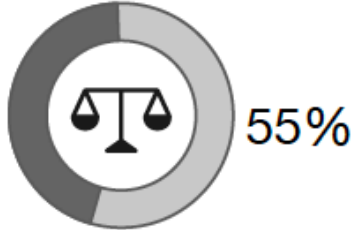


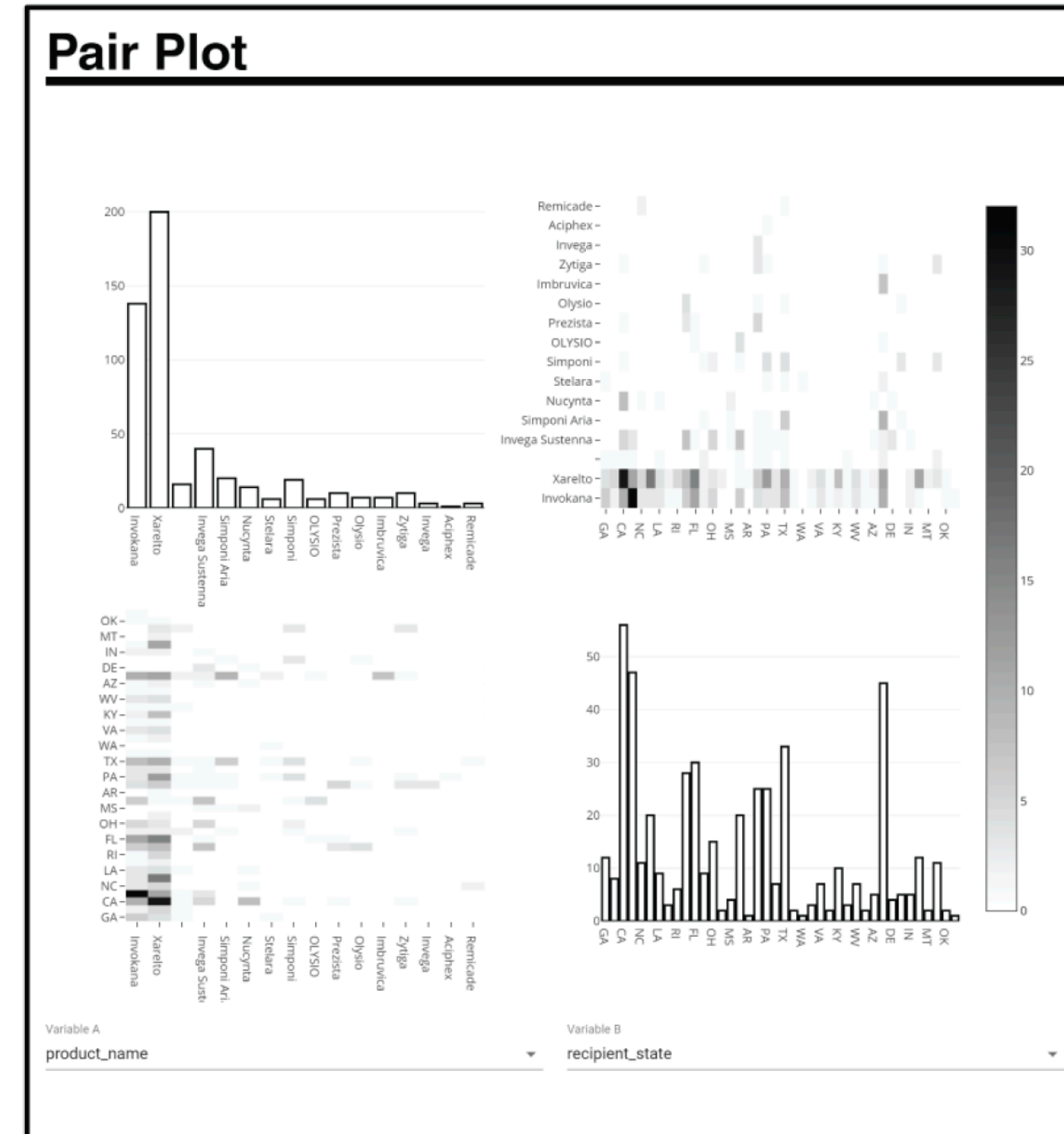
<https://www.fda.gov/food/new-nutrition-facts-label/how-understand-and-use-nutrition-facts-label>



# AI/ML “NUTRITION” LABELS FROM RESEARCH

- i Accuracy
- i Fairness
- i Generalization
- i Transparency
- i Robustness

Generalization	Fairness
	
This model should only be used for recommending property loans.	This model may discriminate certain groups. Read <a href="#">here</a> which groups are affected.
Not unusual <span>i</span>	15% below average <span>i</span>



Seifert, C., Scherzinger, S., & Wiese, L. (2019, 12-14 Dec. 2019). *Towards Generating Consumer Labels for Machine Learning Models*. Paper presented at the 2019 IEEE First International Conference on Cognitive Machine Intelligence (CogMI).

Holland, S., Hosny, A., Newman, S., Joseph, J., & Chmielinski, K. (2018). The dataset nutrition label: A framework to drive higher data quality standards. *arXiv preprint arXiv:1805.03677*.

# 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!

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