An ONC Artificial Intelligence Showcase –

Seizing the Opportunities and Managing the Risks of Use of AI in Health IT

January 14th, 2022

Event Emcee: Stephen Konya

Senior Advisor to the Deputy National Coordinator
for Health IT and Innovation Portfolio Lead

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

The Office of the National Coordinator for Health Information Technology

Agenda at a Glance

Start Time	Agenda Item	Topic
12:00pm EST:	**Opening Plenary**	***Welcoming Remarks***
12:30pm	**AI Showcase Part #1**	***Advancing Responsible Ai in Health IT – Guiding Principles***
1:20pm:	**[5-minute break]**	
1:25pm	**AI Showcase Part #2**	***Transparency and Accountability***
2:20pm	**[10-minute break]**	
2:30pm	**AI Showcase Part #3**	***Evaluating Data Input Needs & Real-World Performance***
3:45pm	**[5-minute break]**	
3:50pm	**Closing Plenary**	***Closing Remarks and A Panel Discussion***
4:30pm	**Event Closes**	

Opening Plenary

Event Emcee:
Stephen Konya, Senior Advisor and Innovation Portfolio Lead,
Office of the National Coordinator for Health IT (HHS/ONC)

Plenary Speakers;
Micky Tripathi, National Coordinator for Health IT,
Office of the National Coordinator for Health IT (HHS/ONC)

Lynne Parker, Director,
National Artificial Intelligence Initiative Office (NAIIO),
White House Office of Science and Technology Policy (OSTP)

Oki Mek, Chief Artificial Intelligence Officer,
Office of the Chief Intelligence Officer (OCAIO),
Office of the Chief Information Officer (HHS/OCIO)

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National Artificial Intelligence Initiative

Lynne Parker, Ph.D.

Director, National Artificial Intelligence Initiative Office

White House Office of Science and Technology Policy

January 2022

National AI Initiative Act of 2020 (NAIIA)

- Became law on January 1, 2021
  - As part of the "*William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021", H.R. 6395, Division E.*

DIVISION E—NATIONAL ARTIFICIAL INTELLIGENCE INITIATIVE ACT OF 2020

SEC. 5001. SHORT TITLE.

This division may be cited as the "National Artificial Intelligence Initiative Act of 2020".

- Bipartisan legislation defining National AI Initiative, with purpose of:
  - Ensuring continued U.S. leadership in **AI research and development** (R&D);
  - Leading world in development and use of **trustworthy AI** systems in public and private sectors;
  - **Preparing present and future U.S. workforce** for integration of AI systems across all sectors of economy and society; and
  - **Coordinating AI research, development, and demonstration** activities among civilian agencies, Department of Defense, and Intelligence Community to ensure that each informs work of the others.

National AI Initiative Office – Central Hub for Coordinating Federal Activities, Outreach

- Launched January 2021, per NAII Act
- Charged with overseeing and implementing the National AI Initiative
- Serves as central hub for Federal coordination and collaboration in AI research, development, and demonstration, as well as with private sector, academia, and other stakeholders involved in the initiative
- Conducts regular public outreach
- Promotes access to the technologies, innovations, best practices, and expertise derived from the National AI Initiative to agency mission and systems across the Federal Government

Agencies Coordinate AI Programs and Activities

National AI Initiative

Prioritize AI R&D
Grow and sustain U.S. research leadership and capacity

Strengthen AI Research Infrastructure
Enhance access to high quality data, models, testbeds, & computing resources

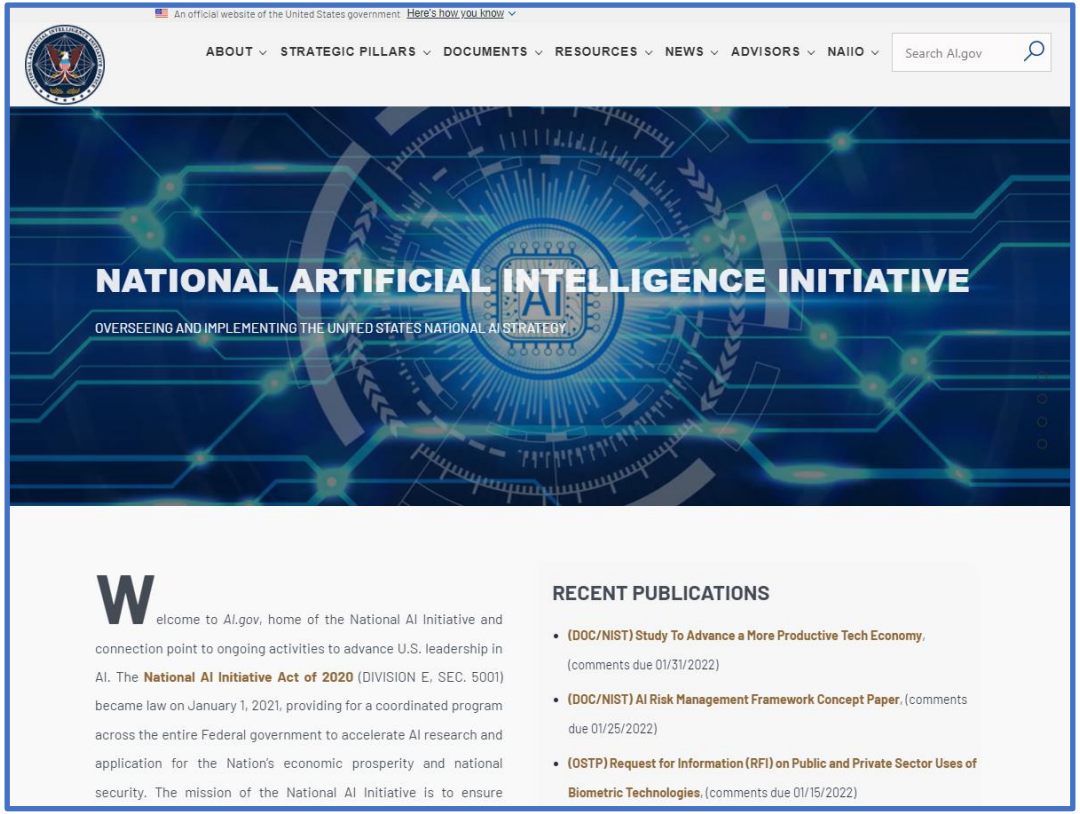
Advance Trustworthy AI
Modernize governance and technical standards for AI-powered technologies, protecting privacy, civil rights, civil liberties, and other democratic values

Leverage AI for Government and National Security
Apply AI to improve provision of government services and national security

Promote International AI Engagement
Engage with like-minded allies to promote a global AI environment supportive of democratic values

Train AI-Ready Workforce
Provide AI-ready education at all levels: K-12, college, re-training, re-skilling, R&D workforce

For more info, check out AI.gov!



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS)

OFFICE OF THE CHIEF ARTIFICIAL INTELLIGENCE OFFICER (OCAIO)

Oki Mek, Chief Artificial Intelligence Officer

January 14th 2022

AI JOURNEY TO-DATE

Enterprise AI Strategy & Draft AI Council Governance Model

The HHS AI strategy and AI Council will lead HHS in achieving its AI ambition through four focus areas that can accelerate AI adoption and scaling across the Department.

ENTERPRISE AI STRATEGY

Together with its partners in academia, industry and government, HHS will leverage AI to solve previously unsolvable problems by ***continuing to lead advances in the health and wellbeing*** *of the American people,* ***responding to the use of AI*** *across the health and human services ecosystem, and* ***scaling trustworthy AI adoption*** *across the Department.*

Develop an AI ready Workforce and Strengthen AI Culture

- Communicate AI trainings, workshops, and recruitment initiatives
- Showcase Department AI priorities and projects spotlights via email blasts/newsletters
- Coordinate AI awareness campaigns and change management communications

Encourage Health AI Innovation and R&D

- Track AI initiatives across key mission areas
- Foster new and public/private partnerships in critical AI priorities
- Communicate emerging AI innovations across health industry

Democratize Foundational AI Tools and Resources

- Develop an AI Community of Practice to share AI best practices and knowledge
- Collate, monitor, and drive awareness of active and planned AI use cases across HHS

Promote Trustworthy AI Use and Development

- Advise on AI policy creation
- Communicate Federal AI mandates and guidance
- Develop Department principles for safe, secure, and ethical AI use

AI DRAFT GOVERNANCE MODEL

AI COUNCIL LEADERSHIP

Chair and **Co-Chair** lead AI strategy implementation by:

- **Managing external communications and coordination**
- **Supporting internal alignment of AI initiatives**

AI COUNCIL

Division representatives provide oversight and guidance for AI adoption by:

- **Providing Governance Support**
- **Cultivating Partnerships**
- **Enabling and Accelerating AI Priorities**
- **Sponsoring an AI Community of Practice**

AI COMMUNITY OF PRACTICE

Division volunteers support a culture of operationalizing AI ambition by:

- **Fostering AI Culture and Awareness**
- **Providing Insights and Recommendations**
- **Supporting Shared Resources**

HHS AI Council: Overview

The HHS AI Council convenes HHS AI Leaders to advance and scale AI adoption across the Department.

OBJECTIVES

Communicate and champion the Department's AI vision and ambition, and govern the implementation of the enterprise AI strategy and key strategic priorities

SCOPE

The AI Council will provide guidance or recommendations related to the development, implementation, and use of AI internally and by external partners

KEY FUNCTIONS

GOVERN IMPLEMENTATION OF HHS AI STRATEGY AND DEVELOP AI GUIDANCE	ENABLE AND ACCELERATE AI PRIORITIES	CULTIVATE PARTNERSHIPS	SPONSOR A COMMUNITY OF PRACTICE (COP)
• Share AI progress with HHS leadership • Provide strategic guidance and policy recommendations • Coordinate across existing governance bodies to regularly align priorities, activities, and perspectives • Assist Op/Staff Divs in compliance with Trustworthy AI principles	• Provide executive guidance on enterprise AI priorities, including development of AI-related policy, and advise on implementation of AI initiatives that support such priorities • Prompt creation of workgroups to support strategic AI initiatives • Maintain awareness of HHS' AI use case and initiative inventory	• Contribute to interagency coordination • Establish forums to engage partners and convene AI interests, needs, and opportunities across the Department and the health and human services ecosystem • Initiate, facilitate, and promote partnerships within government, industry, and academia	• Maximize coordination, support, and active participation from HHS leaders across the enterprise • Foster AI-ready culture by promoting CoP events or work products • Obtain input from CoP on progress updates and AI workforce needs, use cases, emerging priorities, etc. on a routine basis

GENERAL VOTING TOPICS

Issuing formal recommendations

Setting Department-wide AI priorities

Approving cross-HHS AI work products

Improving how the AI Council operates

Trustworthy AI (TAI) Playbook | Overview

The TAI Playbook is designed to support leaders across the Department in applying TAI principles. It outlines the core components of TAI and helps identify actions to take for different types of AI solutions.

PLAYBOOK OBJECTIVES

1. **Promote understanding** of the TAI principles outlined in EO 13960
2. **Provide guidance and frameworks** for applying TAI principles throughout the AI lifecycle
3. **Centralize relevant federal and non-federal resources** on TAI
4. **Serve as a framework for future HHS policies** on TAI acquisition, development, and use

The Playbook is not…

- ⊗ A formal policy or standard
- ⊗ An exhaustive guide to building and deploying AI solutions

INTENDED AUDIENCE

The TAI Playbook is intended for Op/StaffDiv Leadership Teams, including:

OCIO Leadership

Should use the Playbook to…

- **Create Op/StaffDiv-specific policies** related to TAI
- **Evaluate TAI risks** associated with new AI investments

Program/Project Managers

Should use the Playbook to…

- **Incorporate TAI principles into the business requirements** for an AI solution
- **Provide guidance to their teams *before* building an AI solution** about what actions to take
- **Oversee AI projects throughout the lifecycle** to ensure solutions adhere to all TAI principles
- **Identify and mitigate TAI risks** for an AI solution

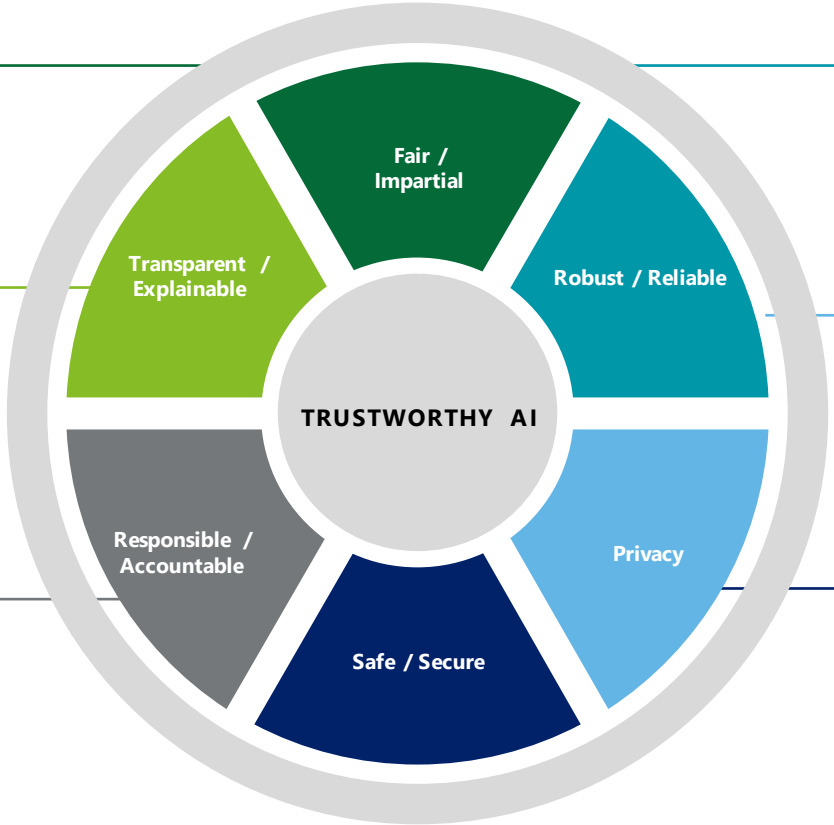
TAI Principles | Overview

The TAI Playbook content is organized by six TAI principles. By designing AI solutions with these principles in mind, OpDivs and StaffDivs can protect against unintended consequences and promote ethical AI decision-making.

Fair / Impartial
AI applications should include internal and external checks to help ensure equitable application across all participants

Transparent / Explainable
All participants should be able to understand how their data is being used and how AI systems make decisions; algorithms, attributes, and correlations should be open to inspection

Responsible / Accountable
Policies should be in place to determine governance and who is held responsible for the output of AI system decisions



Robust / Reliable
AI systems should have the ability to learn from humans and other systems and produce consistent, accurate, and reliable outputs

Privacy
Consumer privacy should be respected, and customer data should not be used beyond its intended and stated use; consumers should be able to opt in / out of sharing their data

Safe / Secure
AI systems should be protected from risks (including Cyber) that may cause physical and/or digital harm

TAI Principles | Alignment to Federal Guidelines

The six TAI principles map to the principles outlined in EO 13960 and OMB Memorandum M-21-06.

TAI Playbook Principles	EO 13960 Principles	OMB M-21-06 Principles
Fair / Impartial	1. Lawful and Respectful of Our Nation's Values	7. Fairness and Nondiscrimination
Transparent / Explainable	5. Understandable 8. Transparent	2. Public Participation 8. Disclosure and Transparency
Responsible / Accountable	6. Responsible and Traceable 7. Regularly Monitored 9. Accountable	5. Benefits and Costs
Safe / Secure	4. Safe, Secure, and Resilient	4. Risk Assessment and Management 9. Safety and Security
Privacy	4. Safe, Secure, and Resilient	9. Safety and Security
Robust / Reliable	2. Purposeful and Performance-Driven 3. Accurate, Reliable, and Effective	3. Scientific Integrity and Information Quality

Additional Cross-Cutting Principles:
1. Public Trust
6. Flexibility
10. Interagency Coordination

HHS AI Website

https://www.hhs.gov/about/agencies/asa/ocio/ai/

1 **AI Statutes and Authorities**

2 **HHS AI Strategy**

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3 **HHS AI Trustworthy Playbook**

4 **Accomplishments**

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5 **AI Activities and Priorities – OMB Data Calls, Community of Practice, AI Council**

AI Showcase Part #1:

Advancing Responsible Ai in Health IT – Guiding Principles

- NIST
- VA NAII
- AHRQ
- Canada Health Infoway
- NHSX
- Linux Foundation
- Connected Health Initiative
- Intermountain Healthcare

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

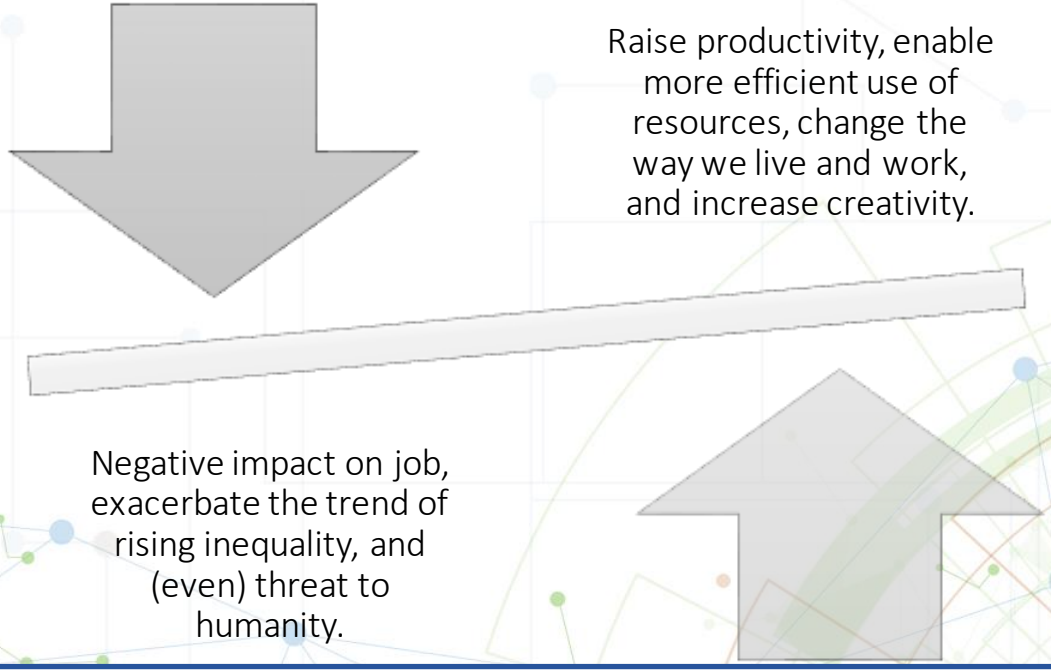
Trustworthy AI @ NIST

Elham Tabassi
Information Technology Laboratory

National Institute of Standards and Technology
U.S. Department of Commerce

January, 2022

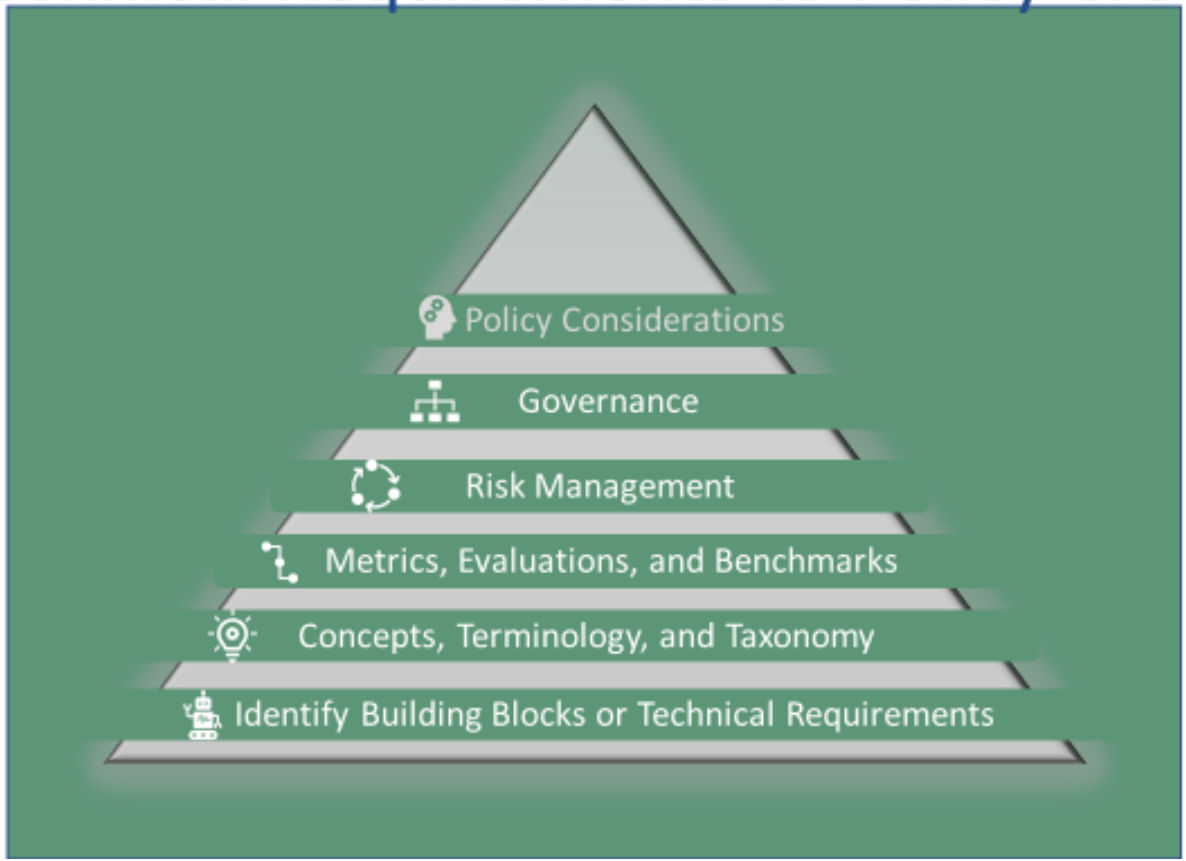
Major Advances in A.I. Continue to Drive Need for Universal Understanding of Risks

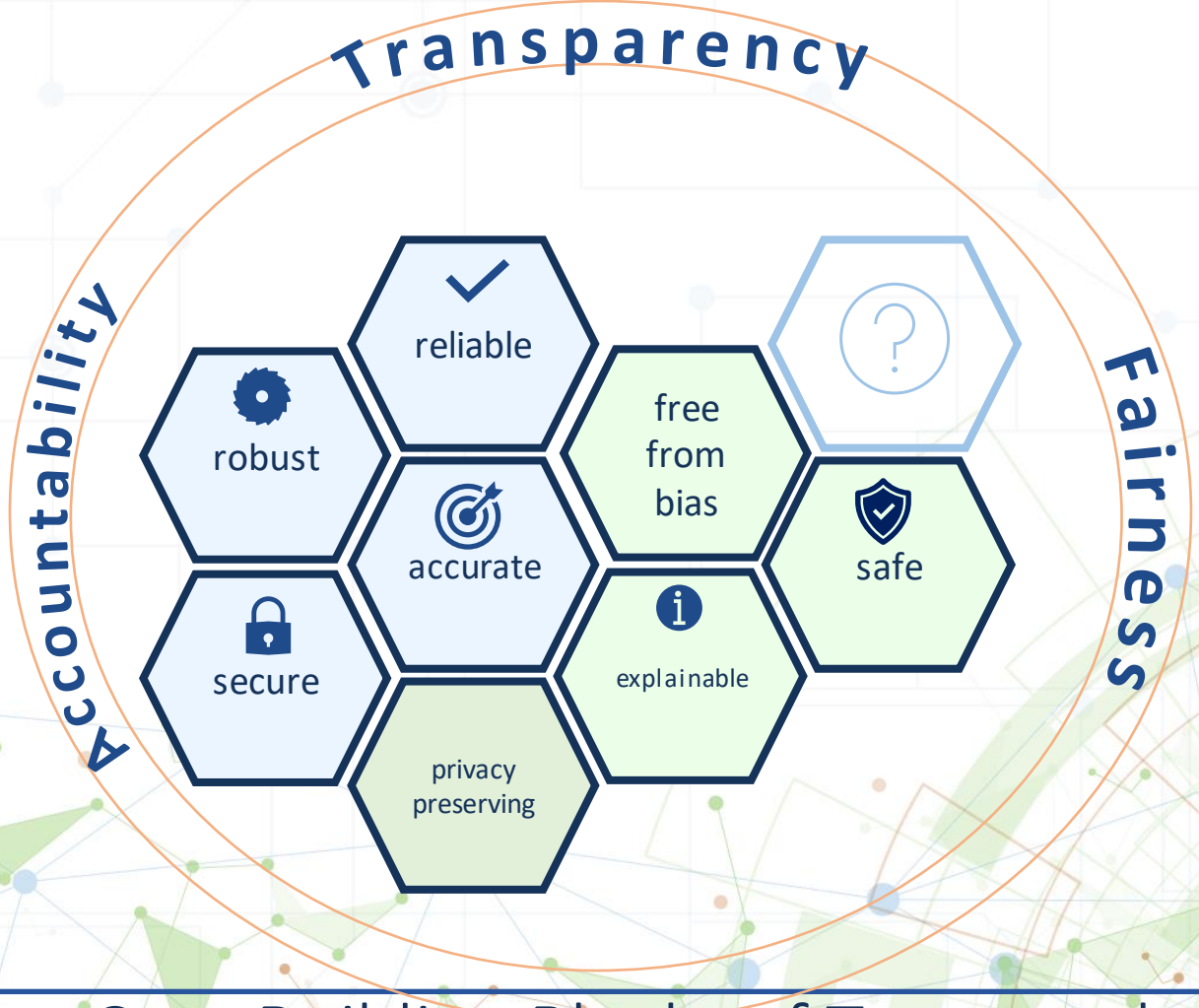


Raise productivity, enable more efficient use of resources, change the way we live and work, and increase creativity.

Negative impact on job, exacerbate the trend of rising inequality, and (even) threat to humanity.

Trustworthy AI's Foundation: From Technical Requirements to Policy Creation



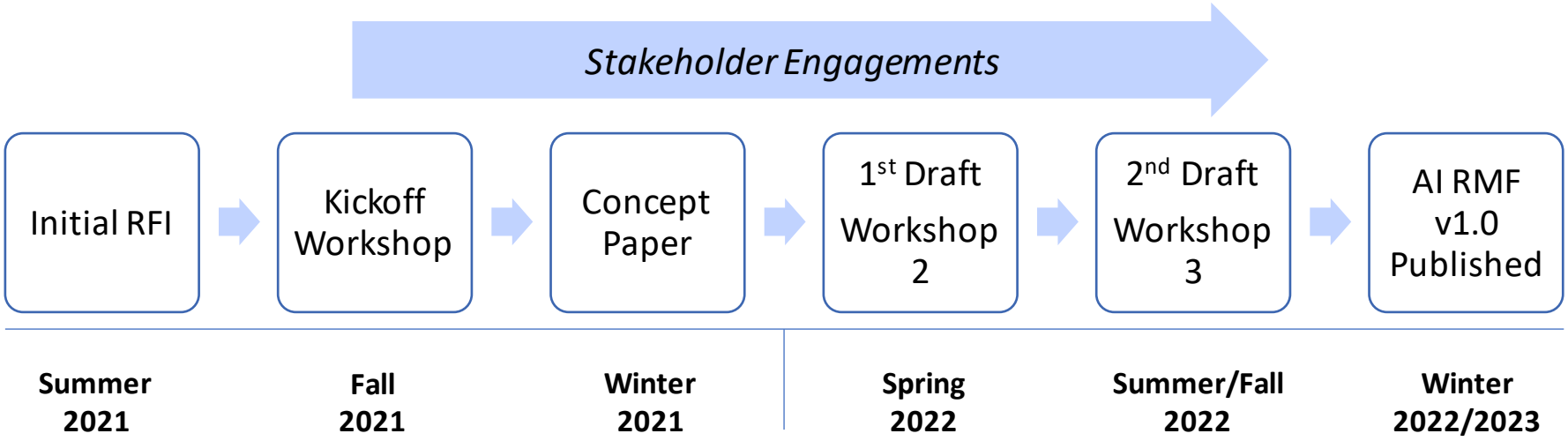


Core Building Blocks of Trustworthy AI

NIST AI Risk Management Framework: Concept Paper *January 2022*

NIST is actively engaging stakeholders to develop a risk management framework to map, measure, manage, and govern risks associated with AI technologies.

AI RMF Stakeholder Engagement Timeline



THANK YOU

Contact us via email at
aiframework@nist.gov

For more info on the NIST AI RMF, visit
https://www.nist.gov/itl/ai-risk-management-framework

Enabling Trustworthy AI:

Experiences from the VA, the Nation's Largest Integrated Healthcare System

Gil Alterovitz, PhD, FACMIA, FAMIA

Why AI at VA?

9,100,000+
patients, making VA the largest integrated healthcare system in the United States

120,000+
doctors and nurses in VA, with nearly 75% of all US doctors and nurses trained in VA hospitals

800,000+
genomic donations tied to medical records, the largest such database in the world

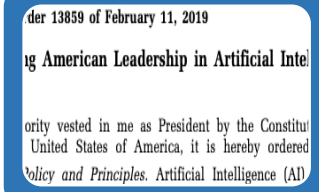
10,000,000,000+
medical images, with 1 billion more per year; one of the world's largest medical image repositories

1,200+
medical facilities across all 50 states and US territories

2,180,000+
telehealth episodes of care per year

727,000+
Veterans served by telehealth per year

Groundwork: Guiding Documents


der 13859 of February 11, 2019

ıg American Leadership in Artificial Intel

ority vested in me as President by the Constitu
United States of America, it is hereby ordered

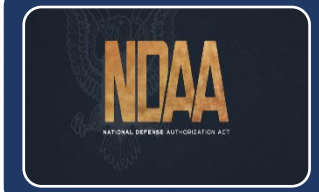
olicy and Principles. Artificial Intelligence (AI)

Executive Orders 13859 and 13960

- Maintaining American Leadership in Artificial Intelligence
- Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government

Strategies

- National AI R&D Strategy (2019)
- VA AI strategy, VA/DOD strategies



2021 National Defense Authorization Act (NDAA)

- NDAA Fiscal Year 2021 called for a National AI Initiative to coordinate AI research and policy across the federal government.

VA AI Strategy

- Set the VA's vision and mission to improve outcomes and experiences for our Veterans by developing trustworthy AI capabilities.
- VA is one of the first federal agencies with an official and explicit AI strategy. Brought together 20+ offices across VA.
- See it here: www.va.gov/guidance

VA and DeepMind

- Predict Acute Kidney Injury (AKI) 48 hours in advance
- Early warning enables time to take preemptive action
- Leverages deep learning

https://www.nature.com/articles/s41586-019-1390-1

> ***"Nonadherence [to medications] can account for… up to 25% of hospitalizations each year in the United States."***

J. Kim, "Medication Adherence: The Elephant in the Room," US Pharmacist, 2018.

Enabled by Artificial Intelligence

State-of-the-art Computer Vision (CV) Technology trained on a combination of the VA, RXNorm, NDC Data Source Formularies and integrated to the needs of an individual

Thank You!

Gil Alterovitz, PhD, FACMIA, FAMIA

Email us at naii@va.gov

Website: National Artificial Intelligence Institute (NAII) (va.gov)

Join the AI@VA Community:

- AI@VA Community SharePoint: AI@VA - Community Home (sharepoint.com)
- AI@VA Community on Teams: https://tinyurl.com/VA-AI-Community
- Subscribe to our newsletter: Join the AI@VA Community



AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ Evidence-based Practice Center (EPC) Review: Examining the Impact of Algorithms on Racial Inequities in Healthcare

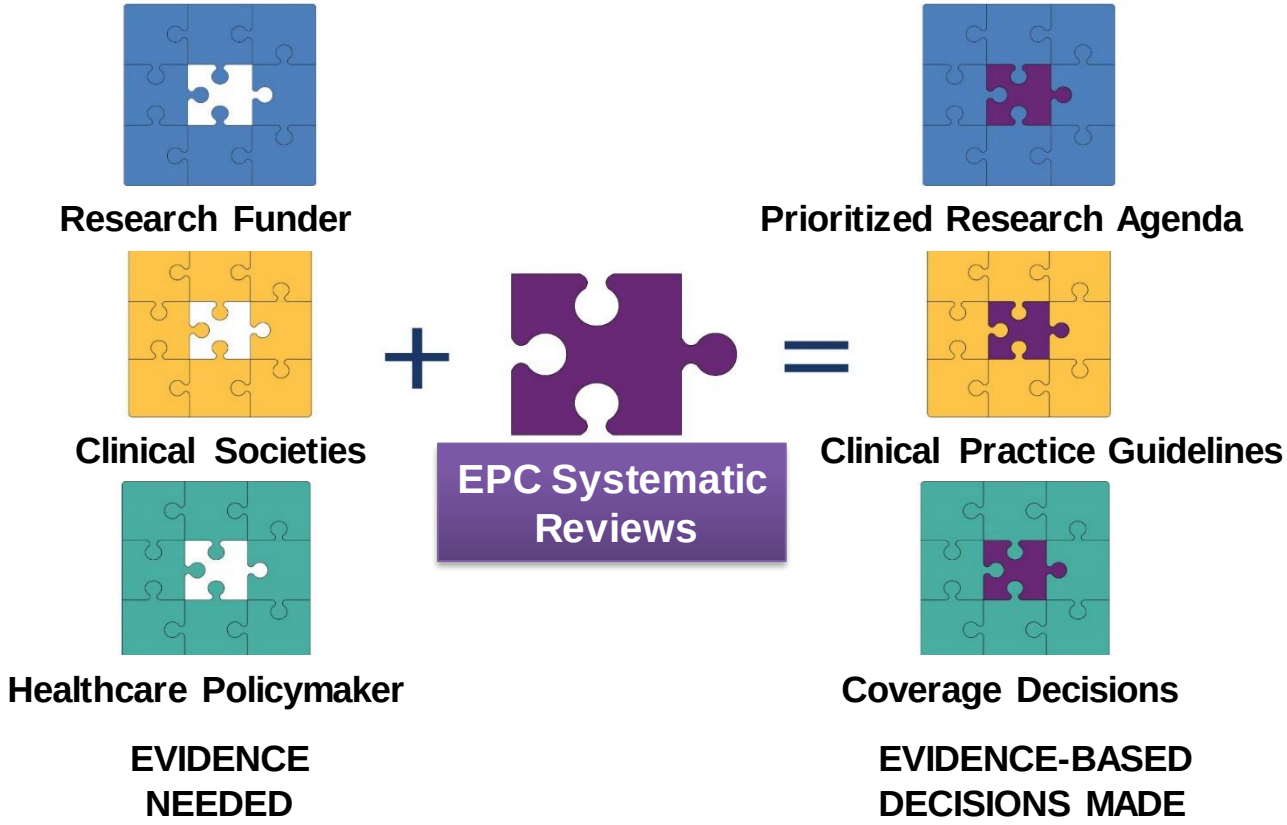
Craig Umscheid, MD, MS
Agency for Healthcare Research and Quality (AHRQ)

ONC AI Showcase
January 14, 2022

Agency for Healthcare Research and Quality (AHRQ) Mission Statement

- To produce evidence to make healthcare safer, higher quality, more accessible, equitable and affordable
- To work with HHS and other partners to make sure that the evidence is understood and used

AHRQ Evidence-based Practice Center (EPC) Program: Partnerships for Impact



New Review: Impact of Algorithms on Healthcare Inequities

- **Congressional Request for Evidence Review**
  - September 2020
  - Senators Warren (MA), Booker (NJ), Wyden (OR), and Representative Lee (CA)

- **AHRQ Request for Information to Inform Planning for Evidence Review**
  - March 2021
  - Included 11 questions gauging awareness of the use of algorithms in healthcare and their potential for introducing racial bias in clinical decision making

- **AHRQ Evidence Review Commissioned**
  - Request For Proposals released March 2021
  - Contract awarded May 2021
  - Public posting of draft key questions Nov 2021
  - Protocol finalized Jan 2022

Request For Information

- 42 responses totaling 485 pages
- Respondents included:
  - 18 clinical and professional societies
  - 9 healthcare technology groups
  - 7 academic organizations
  - 4 federal and state agencies
  - 1 payer organization
  - 4 private citizens

Early Themes from Request For Information (RFI)

- 18 algorithms identified that could potentially result in racial disparities in care
- Bias could result from algorithms even when race/ethnicity not explicitly included
- Heterogeneity and lack of standardization in how race information collected and defined
- Algorithms often developed using data from populations not representative of those to whom algorithm applied
- Organizations described efforts to update algorithms in use and examine presence of bias
- Some respondents cited research demonstrating disparities in care resulting from algorithms
- Respondents suggested many likely unaware of widespread use of clinical algorithms and their potential bias

Evidence Review Key Questions

Key Question 1. What is the evidence that healthcare algorithm-informed decision tools contribute to racial/ethnic disparities in access to care, quality of care, and health outcomes?

Key Question 2. What approaches have been used to mitigate bias in the development, validation, and implementation of healthcare algorithm-informed decision tools?

https://effectivehealthcare.ahrq.gov/products/racial-disparities-health-healthcare/draft-

Next Steps

- Public posting of draft report anticipated Summer/Fall 2022
- National consensus conference Fall/Winter 2022
- Completion of final report anticipated Fall/Winter 2022

Acknowledgements

- **Anjali Jain, MD**
  Medical Officer, AHRQ
- **Christine Chang MD, MPH**
  Associate Director, EPC Division, AHRQ
- **Arlene Bierman, MD, MS**
  Director, Center for Evidence and Practice Improvement, AHRQ
- **ECRI Institute – Penn Medicine Evidence-based Practice Center**

For More Information

- Craig Umscheid, MD, MS, Director, EPC Division, AHRQ
  - Craig.Umscheid@ahrq.hhs.gov
- Effective Health Care website
  - https://effectivehealthcare.ahrq.gov/
- To sign up for AHRQ notifications
  - https://effectivehealthcare.ahrq.gov/email-updates

Canada Health Infoway

Embarking on an AI Enabled Health Care Solution Journey

Advancing Responsible AI in Health IT

January 14, 2022

Karen Jacquart, BASc, MBA
Innovative Technologies, Canada Health Infoway

AI In Canada

- Canada has a deep history in AI – and was the first country to develop a National AI Strategy in 2017 through the Canadian Institute For Advanced Research (CIFAR)
- The main component of the AI Strategy is the CIFAR AI Chairs Program. This program is affiliated with the Canada's three leading AI Institutes - Vector Institute (Toronto), MILA (Montreal) and Amii (Edmonton), and is focussed on talent development and retention. 30% of the Chairs are affiliated with health care.
- In July of 2020 CIFAR assembled an AI for Health (AI4H) Task Force to assess the opportunities and challenges for AI to impact the health sector.
- Canada's single payor system and diverse population should give Canada an advantage with respect to access and quality of training data.
- Focus was on three potential application areas: health care delivery, disease prevention and public health, discovery and development of diagnostics
- Identified three areas for action: AI data infostructure, accelerated development and **deployment**, and a development of a Pan-Canadian AI4H Strategy.

Toolkit for Implementers of AI in Health Care

AUDIENCE: HEALTH CARE DELIVERY ORGANIZATIONS THAT ARE EARLY IN THEIR AI JOURNEY
ROLES: AI PROJECT LEADS, CIO'S, PRIVACY, SECURITY, LEGAL, COMPLIANCE, ETHICISTS, CLINICIANS, PROJECT SPONSORS, IT/IM SPECIALISTS

Module 1: An Introduction to AI in Health Care

Module 2: Understanding Key Risks of AI in Health Care

Module 3: Emerging Regulation of AI

Module 4: Identifying Strategic Opportunities and Investments in AI

Module 5: Change Management for AI Adoption in the Health Sector

Module 6: AI Governance: Structures, Roles and Responsibilities

Annexes 1-6: Reading List, Privacy Considerations, Health Privacy Laws, Synthetic Data and Federated Learning, Spotlight on AI Innovation

Canada Health Infoway

What Else Might You Want to Know?

Currently:

- Soft launch on December 1, 2021
- There are 6 modules, 9-15 pages each ~90 pages in total
- The Toolkit is free and downloadable in French and English, as a complete Toolkit or by individual module

What's Next:

- We will be holding a free deep dive webinar series weekly starting Feb. 3rd, 2022 (open to the public), come to one or come to all
- We are soliciting feedback for future versions of the Toolkit – *what does the implementer community want to know more about when implementing responsible AI?*

Canada Health Infoway

Thank you

Download: infoway-inforoute.ca/AIToolkit

Please get in touch: innovation@infoway-inforoute.ca

Visit OUR WEBSITE
infoway-inforoute.ca

VISIT OUR SURVEY WEBSITE
insights.infoway-inforoute.ca/

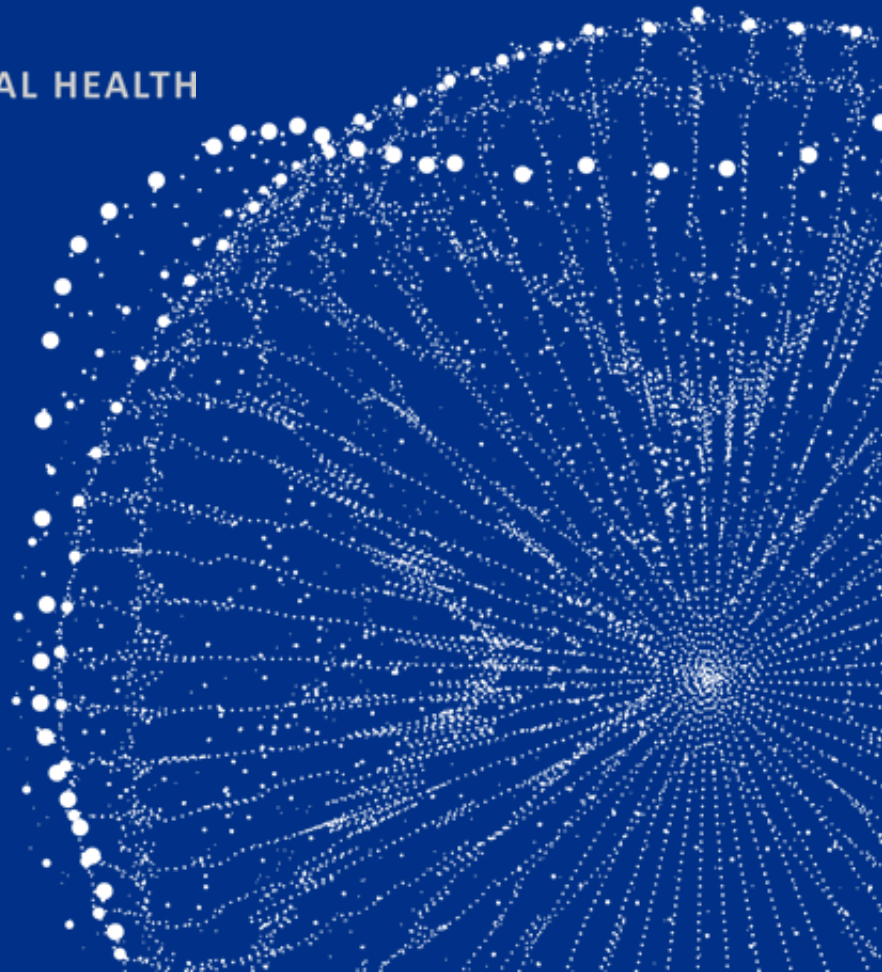
Let's Connect on LinkedIn
linkedin.com/company/canada-health-infoway/

Let's Connect on Twitter
@infoway

NHS X

GLOBAL DIGITAL HEALTH PARTNERSHIP

Turning AI policy advice into action



NHS AI Lab | January 2022

GDHP AI Recommendations

GLOBAL DIGITAL HEALTH PARTNERSHIP

NHS X

Policy Paper Development | Rapid Literature Review | International Stakeholder Interviews | Analysis

Leadership & oversight

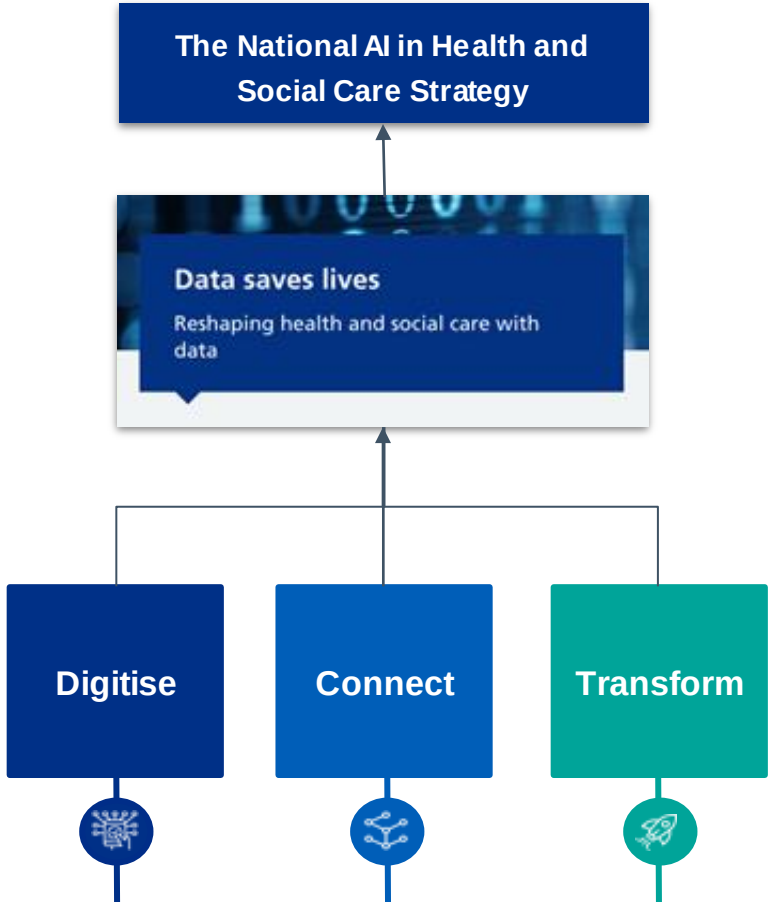
Enabling ecosystem

Accepted standards

Engagement & collaboration

Authors: Kassandra Karpathakis, Lisa Murphy, Abhishek Mishra, Jess Morley

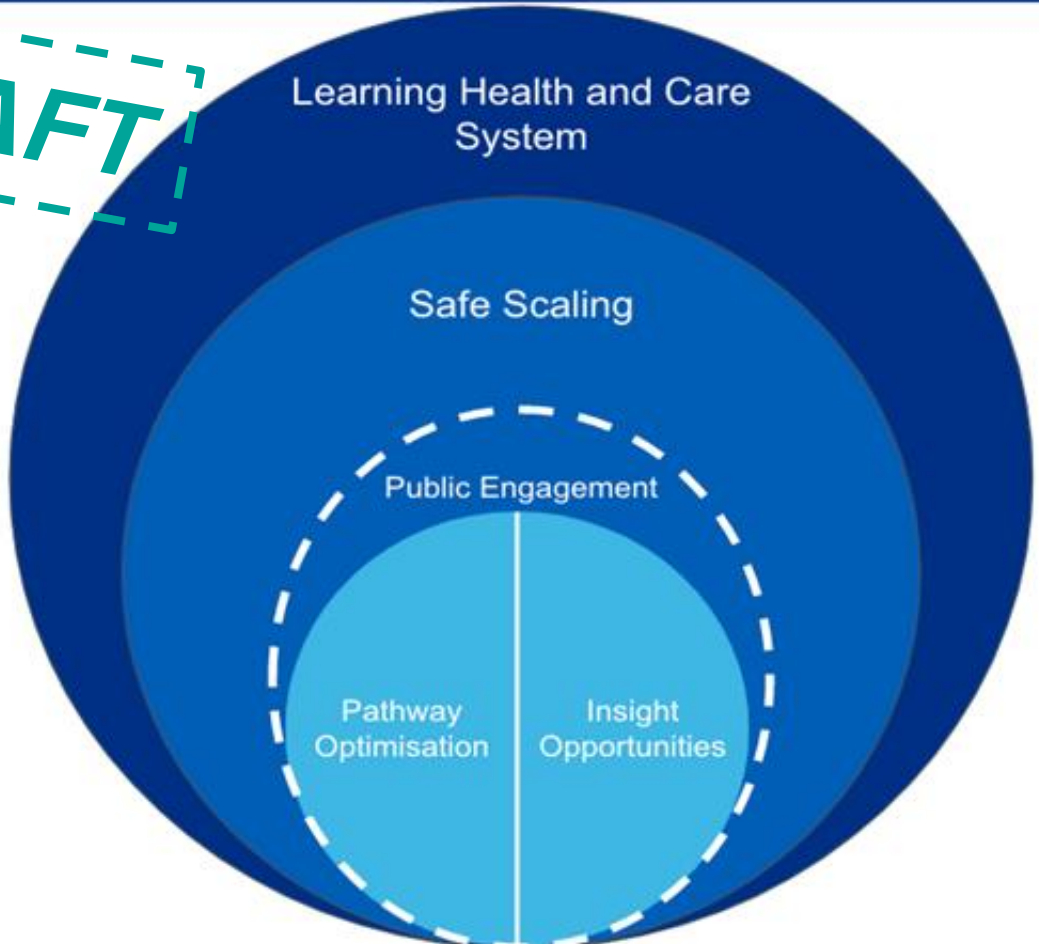
The AI ecosystem in health and care



Our vision for

DRAFT

"By 2030, the UK has a **learning health and care system**, delivering **better outcomes for the public**, enabled by the use of **safe, ethical and effective**, artificial intelligence, setting an example to the world."



Questions?

If you have any further questions, comments, or feedback please contact the Head of AI Strategy, Leanne Summers:

leanne.summers@nhsx.nhs.uk

Join the AI Lab Virtual Hub

https://www.nhsx.nhs.uk/ai-lab/ai-lab-virtual-hub/


Linux Foundation Public Health (LFPH)
Overview for public health authorities, prospective members, and project maintainers
www.lfph.io
LF PUBLIC HEALTH

About Linux Foundation Public Health (LFPH)

- LF Public Health's mission is to use open source software to help public health authorities (PHAs) around the world.
- Founded in summer of 2020, the initial focus of LFPH has been helping PHAs deploy an app implementing the Google Apple Exposure Notification (GAEN) system.
- LFPH brought in the Covid Credentials Initiative to take lead on creating interoperable standards for sharing pandemic-related health data.
- As the organization grows we are moving into other areas of public health that can take advantage of open source innovation.

Why AI/ML in Healthcare?

- Software as a second pair of eyes in the ICU
- Personalized Treatments
- Reduce Administrative Burden
- Mining the Data Ocean
- Recording digital notes *e.g.* transcription
- Operations, such as scheduling
- Automation support
- Coding and billing

- Predictive Analysis: *e.g.* COVID surges
- Treatment recommendations – but not just CDS – learning constantly
- Monitoring patients: hospitalized and ambulatory
- Guiding surgical care: *e.g.* Black Box project
- Population Health

Challenges

- Data ocean pollution
- Transparency of algorithms: proprietary?
- Patient privacy
- Liability issues
- CYBERSECURITY

Healthcare & Public Health Sector Coordinating Councils

Healthcare Tech Risk
AIML Bulletin – Sub-Group Assignments

Last Updated: 2021-07-30 REV 11

GROUP	CONCERN #1: Organizational Outcomes & Expectation for Performance, Quality & Precision not clearlyarticulated
MEMBERS	Penny Chase, MITRE Catherine Lowe, MedSec
SME	Dr. Flo Reeder, MITRE

GROUP	CONCERN #2: Accountability for Outcomes Not Defined
MEMBERS	Ed Gaudet, Censinet Julie Sisk, USRadiology
SME	Franciso Delgado, FDA Aaron Heath, Syneos Health Barton Rhodes, Lacework

GROUP	CONCERN #3: Transparency for Model Assurance is Missing
MEMBERS	Nimi Ocholi, Medtronic
SME	James Harbinson, JHUAPL Fotios Chantzis, OpenAI

GROUP	CONCERN #4: Dubious Quality of Source Data
MEMBERS	Mac Stevens, Spok
SME	Dr. Sven Cattell, AI Village Dr. Arvind Rao, U of Mich

GROUP	CONCERN #5: Absence of Regulatory Oversight
MEMBERS	Chris Reed, Medtronic Christine Sublett, Sublett Consulting
SME	Francisco Delgado, FDA

GROUP	GLOSSARY OF TERMS
WHO	Kenneth Wilder, ClearDATA

GROUP	CONCERN #6: Lack of Business Leader Knowledge
MEMBERS	Jim St. Clair, LFPH
SME	Aaron Heath, Syneos Health Barton Rhodes, Lacework

GROUP	CONCERN #7: Unintended Consequences -Change Management
MEMBERS	Julie Sisk, USRadiology Bill Proffer, Leidos
SME	Hugo Espiritu, JHUAPL

GROUP	CONCERN #8: ADVERSARIAL – Data Input Poisoning
MEMBERS	Mac Stevens, Spok Michael Holt, Virta Labs Julie Sisk, USRadiology Jim St. Clair, Lumedic
SME	Troy Adams, HC3

COMPLETED

GROUP	CONCERN #9: ADVERSARIAL – Information Leakage - Inversion and Inference Attacks
MEMBERS	Jon Moore, Clearwater Regina Farmer, McKesson
SME	Troy Adams, HC3 Dr Flo Reeder, MITRE

GROUP	INTRODUCTION
WHO	TG-6- Mark Jarrett, Northwell Health

GROUP	FINAL LAYOUT/DESIGN
WHO	TBD

FINAL PRODUCT

LF AI & Data: Trusted AI Committee

October 2019:

Trusted AI Committee Established by LF AI Foundation

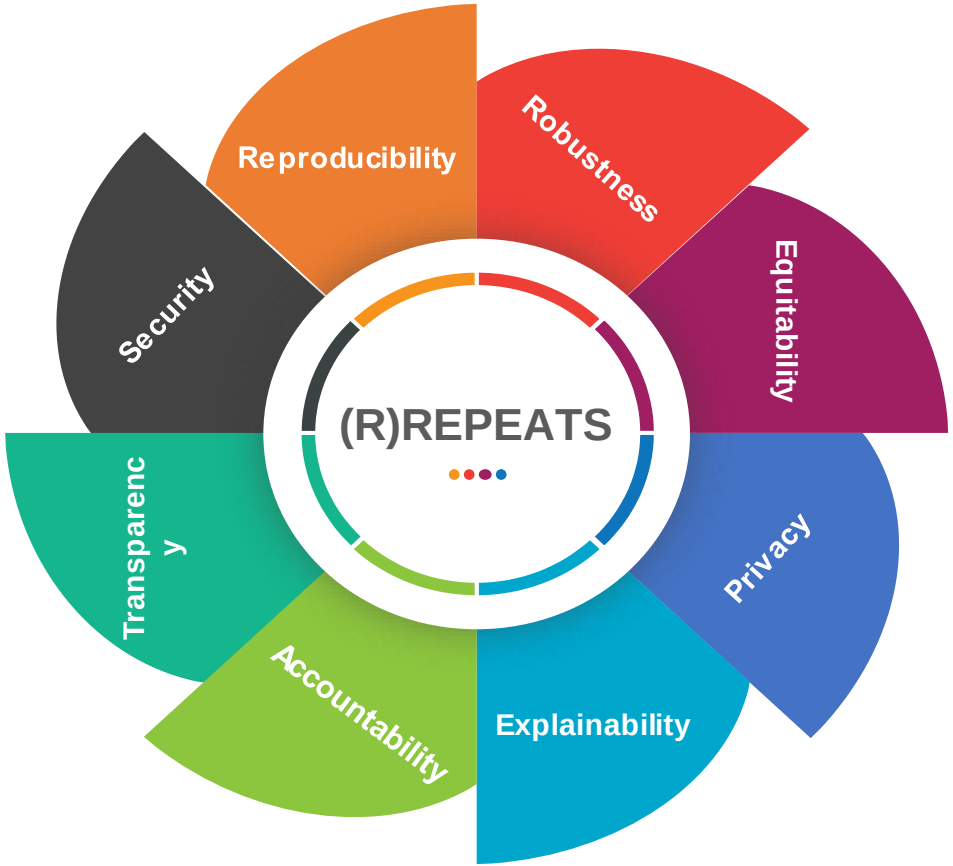
A global group working on policies, guidelines, tools and use cases by industry to ensure the development of trustworthy AI systems and processes to develop them continue to improve over time.

February 2021:

LF AI & Data Announces Principles for Trusted AI

The 8 LF AI & Data Principles for Trusted AI – (R)REPEATS

- The principles are of equal importance and value.
- No principle is of higher priority than another.
- The principles are related to each other.



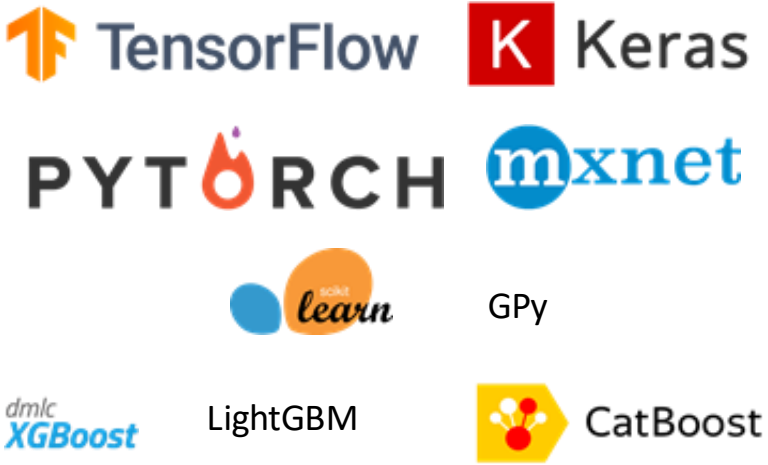
LF AI & DATA

LF AI & Data Projects - Tools and Techniques

- Trusted AI Tools (AI Fairness, AI Explainability, Adversarial Robustness)
- Emerging DataOps activities in LF AI & Data
- Trusted AI and **RREPEATS**

Adversarial Robustness Toolbox (ART)

ART is a Python library for machine learning security

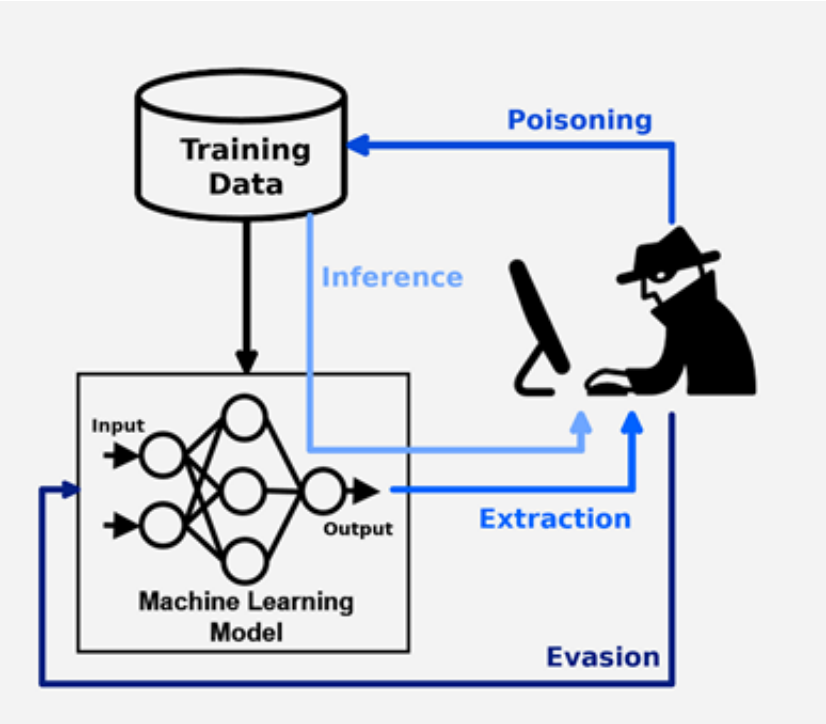


- github.com/Trusted-AI/adversarial-robustness-toolbox
- Provides tools to developers and researcher
- Evaluating, Defending, Certifying and Verifying of machine learning models and applications
- **All Tasks:** Classification, Object Detection, Generation, Encoding, Certification, etc.
- **All Frameworks:** TensorFlow, Keras, PyTorch, MXNet, scikit-learn, XGBoost, LightGBM, CatBoost, GPy
- **All Data:** images, tables, audio, video, etc.

Adversarial Threats to Machine Learning

Adversarial threats against machine learning models and applications have a wide variety of attack vectors.

- Evasion: Modifying input to influence model
- Poisoning: Modify training data to add backdoor
- Extraction: Steal a proprietary model
- Inference: Learn information on private data



ART Community – Contributors and Tools

ART Adopters and Contributors

- IBM
- Microsoft
- Troj AI
- Two Six Labs, LLC
- Kyushu University
- Intel Corporation
- University of Chicago
- The MITRE Corporation
- General Motors Company
- AGH University of Science and Technology
- Rensselaer Polytechnic Institute (RPI)
- IMT Atlantique

2.5K GitHub Stars

150K Downloads

8K+ Commits

Armory

- Adversarial Robustness Evaluation Test Bed
- Run evaluations with ART locally or scaled in the cloud using Docker containers
- github.com/twosixlabs/armory

Counterfit

- Command line tool to simplify running evaluations with ART in terminals
- github.com/Azure/counterfit

ai-privacy-toolkit

- Tools for privacy and compliance of AI models
- End-to-end privacy evaluation and mitigation of privacy risks
- github.com/IBM/ai-privacy-toolkit

LF AI & DATA

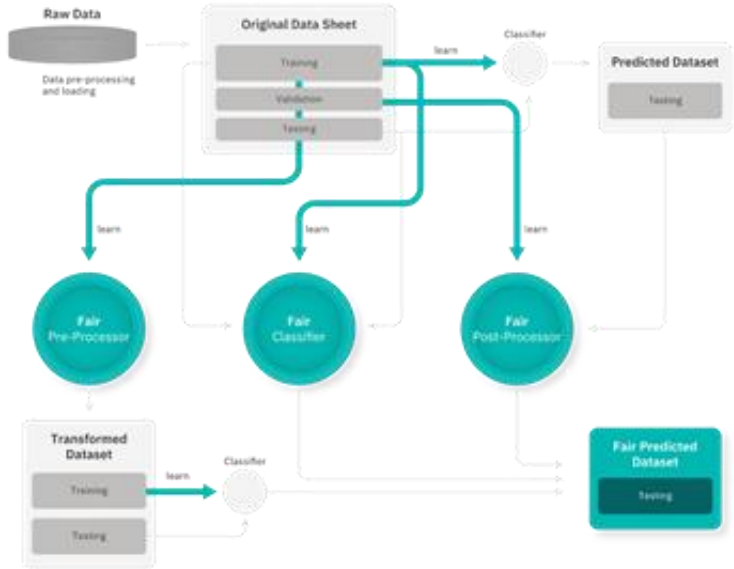
AI Fairness 360

AIF360 toolkit is an open-source library to help detect and remove bias in machine learning models. AIF360 translates algorithmic research from the lab into practice. Applicable domains include finance, human capital management, healthcare, and education.

The AI Fairness 360 Python package includes a comprehensive set of metrics for datasets and models to test for biases, explanations for these metrics, and algorithms to mitigate bias in datasets and models.

Toolbox
Fairness metrics (70+)
Fairness metric explanations
Bias mitigation algorithms (10+)

Demo: http://aif360.mybluemix.net/



AI needs to explain its decision

- One explanation does not fit all
- Different stakeholders require explanations for different purposes and with different objectives, and explanations will have to be tailored to their needs.
- End users/customers (trust)
  - Doctors: Why did you recommend this treatment?
  - Customers: Why was my loan denied?
  - Teachers: Why was my teaching evaluated in this way?
- Gov't/regulators (compliance, safety)
  - Prove to me that you didn't discriminate.
- Developers (quality, "debuggability")
  - Is our system performing well?
  - How can we improve it?

AI Explainability 360 (AIX360)

AIX360 toolkit is an open-source library to help explain AI and machine learning models and their predictions. This includes three classes of algorithms: local post-hoc, global post-hoc, and directly interpretable explainers for models that use image, text, and structured/tabular data.

The AI Explainability360 Python package includes a comprehensive set of explainers, both at global and local level.

Toolbox

- Local post-hoc
- Global post-hoc
- Directly interpretable

Demo
http://aix360.mybluemix.net

Summary of Trusted AI Projects in LF AI & Data

https://adversarial-robustness-toolbox.org/

https://ai-fairness-360.org/

https://ai-explainability-360.org/

ART	Very strong growth and adoption	V1.6.2 released	2.3K GitHub Stars 150K Downloads 8K+ Commits
AIF360	Strong growth trajectory	V0.4.0 released	1.4K GitHub Stars 330+ Commits
AIX360	Used extensively within enterprises	V0.2.1 released	~850 GitHub Stars, 10K downloads/mon 240+ Commits

Thank You!

Jim St.Clair

Executive Director

Linux Foundation Public Health

www.lfph.io

jstclair@linuxfoundation.org

LF PUBLIC HEALTH

ONC Artificial Intelligence Topic #1 "Advancing Responsible Ai in Health IT – Guiding Principles"

Digital Health Ecosystem Consensus Recommendations for Responsible Health AI Governance

January 14, 2022

Brian Scarpelli
Senior Global Policy Counsel
Connected Health Initiative

The Connected Health Initiative

- Not-for-profit multi-stakeholder consensus advocacy effort to advance uptake of digital health tools widely
- Intersection of medical/health and technology communities:
  - Reimbursement/payment
  - Privacy/security
  - FDA regulation of digital health
  - Health data interoperability
  - The role of AI/machine learning in care delivery
- Advocate before Capitol Hill, US agencies, European Commission, OECD/UN, etc.
- Active in key public-private initiatives (Health Sector Coordinating Council, etc.)
- www.connectedhi.com

About the Connected Health Initiative

ConnectedHealth

Digital Health Ecosystem Consensus Recommendations for Responsible Health AI Governance

- The responsible development and deployment of health AI is a shared obligation for:
  - Developers of AI innovations
  - Providers and payers
  - Regulators (at all levels)
  - Accrediting and licensing bodies, and medical specialty societies and boards
  - Academic and medical education institutions
- Ultimately, AI systems must align with the **Quadruple Aim**:
  - Reduce costs
  - Improve population health
  - Improve patient experience and well-being
  - Improve care team experience and well-being

Digital Health Ecosystem Consensus Recommendations for Responsible Health AI Governance

Responsible health AI governance must address:

- Research
- Quality Assurance and Oversight
- Thoughtful Design
- Access and Affordability
- Ethics
- Bias mitigation
- Modernized Privacy and Security Frameworks
- Collaboration and Interoperability
- Workforce Issues
- Education

CHI Health AI Task Force Resources

- **Health AI Policy Principles:** https://bit.ly/3m9ZBLv
- **Why AI? Considerations for Use of Artificial Intelligence in States' Medicaid and CHIP Programs:** https://bit.ly/2Y2FJle
- **Good Machine Learning Practices for FDA-Regulated AI:** https://bit.ly/2YaYljk
- **Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem:** https://bit.ly/3n36WO5

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517-507-1446 | bscarpelli@actonline.org
Connected Health Initiative (www.connectedhi.com)
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Gregory S. Nelson

Intermountain Healthcare

University of Georgia
PhD, ABD Social Psychology

Duke University – Fuqua School of Business,
M.S., Clinical Informatics, Healthcare Analytics

University of California, Santa Cruz
B.A. Social Psychology, Quantitative Methods

AVP Analytic Services: Intermountain Healthcare

VP Analytics & Strategy: Vidant Health

Adjunct Faculty: Duke University

Founder and CEO ThotWave Technologies

Author: The Analytics Lifecycle Toolkit

Intermountain Healthcare

Delivering on the Promise of Responsible AI

Seizing the Opportunities and Managing the Risks of Use of AI in Health IT
An ONC Artificial Intelligence Showcase

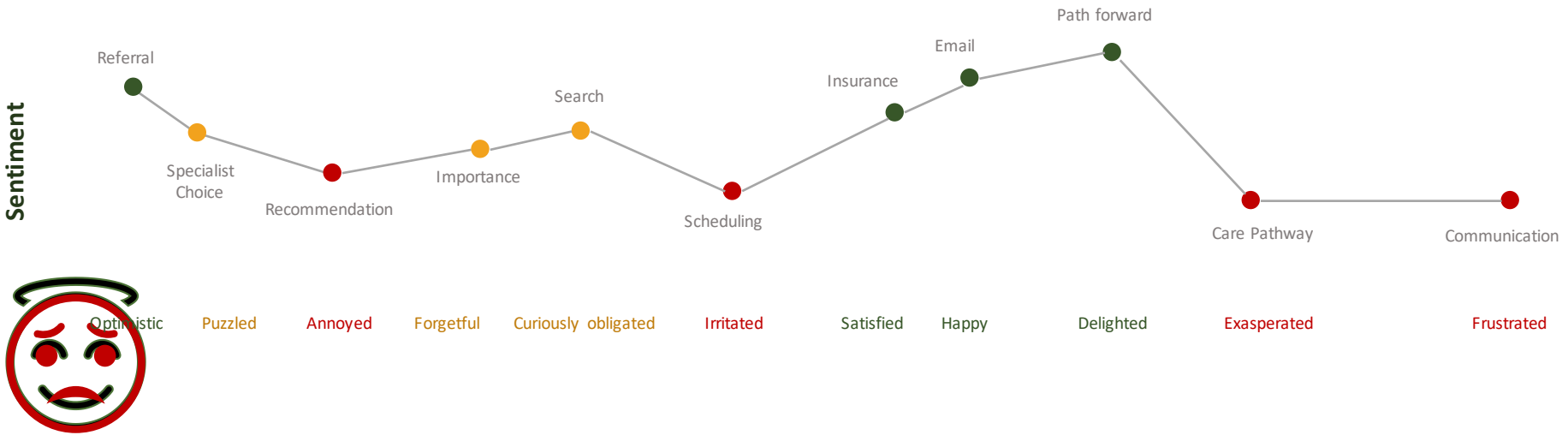
Greg Nelson *FACHE, MMCi, CHCO, CPHIMS*
AVP, Analytics Services – Intermountain Healthcare

Meet Shakira, Age 34

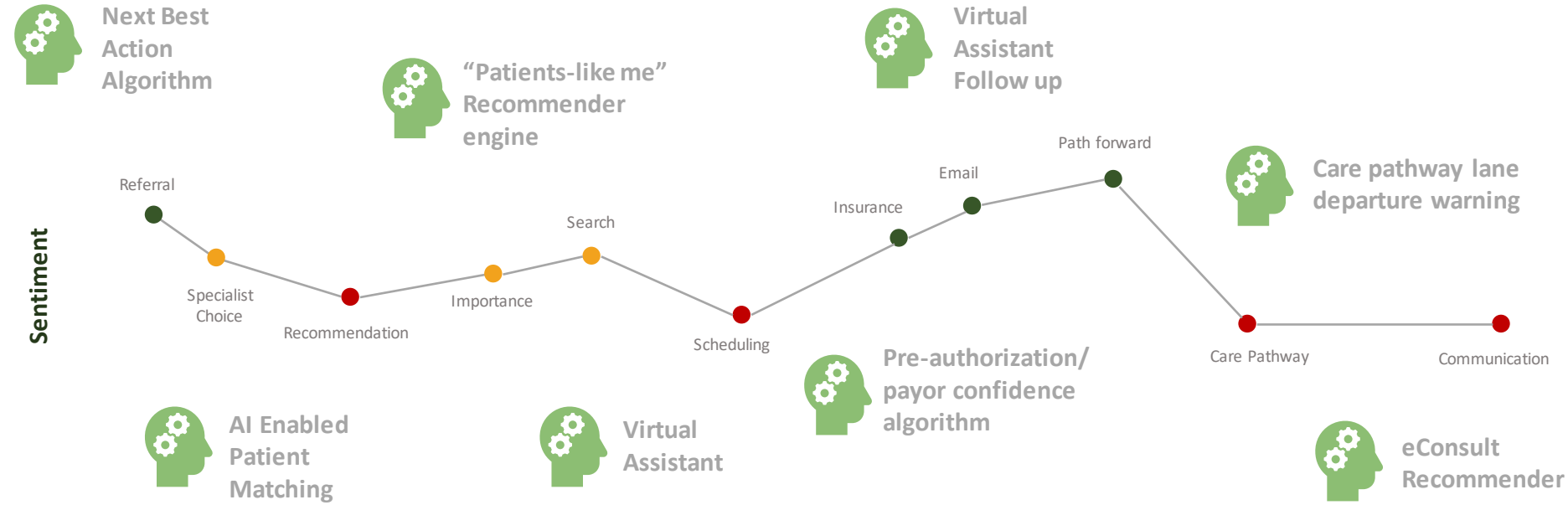
- Shakira presents at an Urgent Care for skin concern
- Physician findings indicate possible melanoma
- Patient needs dermatology consult ASAP
- Physician fills out referral paper
- Paper gets lost
- Patient care delayed by several months
- Patient finally seen by a dermatologist and diagnosed with metastatic melanoma

Shakira's Referral Journey Map

Journey mapping is the process of illustrating a **complete** story about the **relationship** – and **resulting experience** – that unfolds over time between an individual and a system, service, product, organization…



AI-Enabled Process

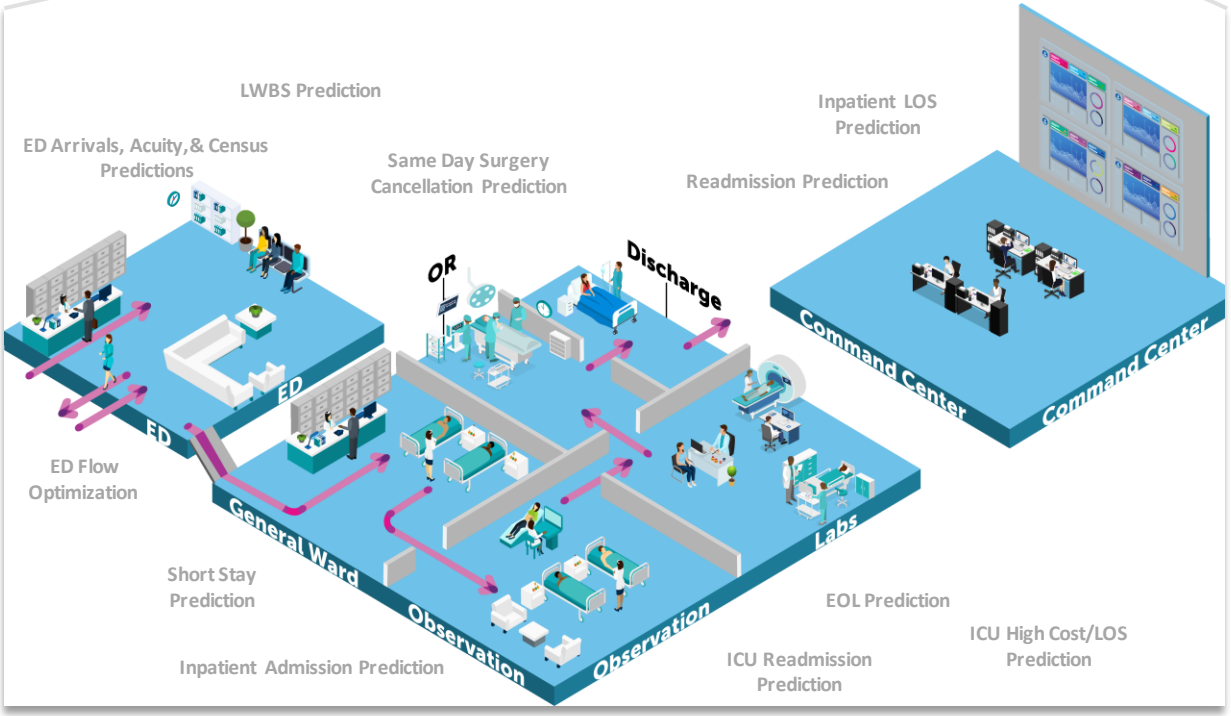


Generation **next** ought to be systems of intention, insight and cognition – systems that know what we want, help us see what we otherwise wouldn't see and help us think.

Cris Ross
Mayo Clinic

Opportunity Landscape

Well-Care | Prevention | Pre-Diagnosis | Acute Care | Chronic Care | Palliative Care



Intermountain® Healthcare

~~What is true~~ what would have to be true?

Inspired by “A Simple Nuance that Produces Great Strategy Discussions” by Roger L. Martin

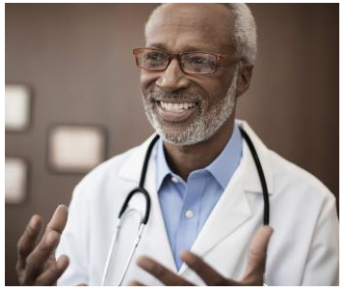
Responsible might mean different things

Patient

Proven & Private

Community

Fair & Ethical



Provider

Trustworthy & Involved

Caregiver

Transparent & Validated

Responsible AI is a framework for deploying artificial intelligence in an ethical, equitable, and transparent way. Using AI responsibly is the act of making sure we always couple AI solutions with these key values in order to identify and avoid unintended consequences.

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AI Playbook: Building Trust and AI Literacy

TABLE OF CONTENTS

"AI is a device or product that can imitate intelligent behavior or mimics human learning and reasoning.

The U.S. Food and Drug Administration (FDA)

* The FDA approved the first deep learning algorithm for cardiac imaging built by Arterys in 2017. Today, the agency has cleared another 126 smart algorithms.

Our AI XLA

Experience Level Agreement

1. ***Strategic Alignment***
   Opportunities for advanced analytics will be evaluated for their alignment to strategy and impact to mission.

2. ***Product Co-Creation***
   As models are developed, we will engage with clinical and operational caregivers to ensure they are built with the caregiver in mind to help improve, not impede the process.

3. ***Model Validation***
   All models will be designed using rigorous verification and validation procedures to ensure that each step in the develoment of the algorithm did not introduce bias or systematic error.

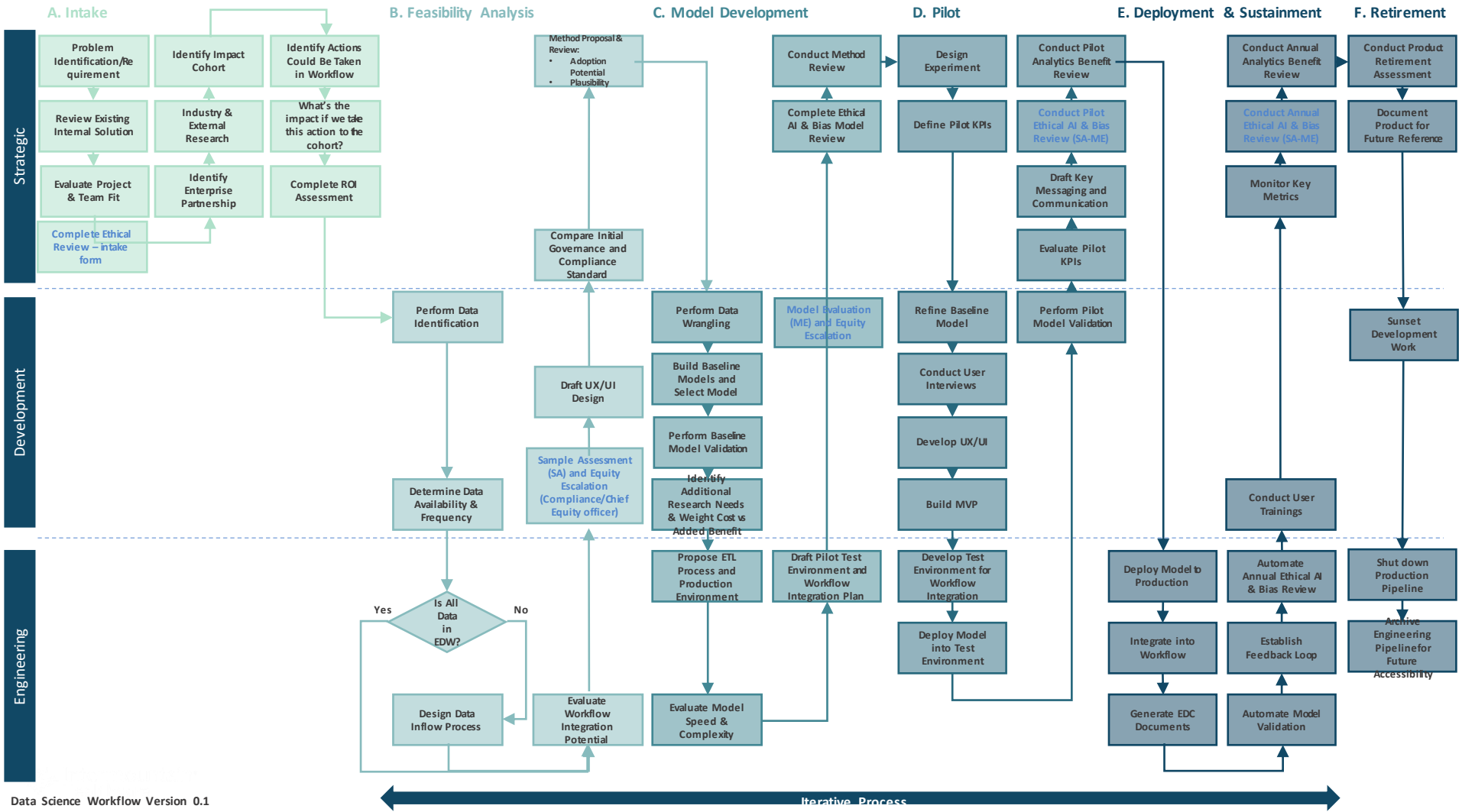
4. ***Designed for Diversity***
   Whether internally developed or externally sourced, all algorithms will be tested for inherent bias in the underlying data or predictive capabilities.

5. ***AI Catalog/Model Cards***
   All advanced analytics algorithms will be cataloged according to their intended use, testing procedures, monitoring requirements, and operational impact(s).

6. ***Model Drift***
   After models have been put into production, we will proactively monitor them to ensure they continue to provide predictive value and will re-tune, replace, or retire as necessary.

How we are executing against that vision

Intermountain® Healthcare


A. Intake
B. Feasibility Analysis
C. Model Development
D. Pilot
E. Deployment & Sustainment
F. Retirement
Strategic
Development
Engineering
Problem Identification/Requirement
Identify Impact Cohort
Identify Actions Could Be Taken in Workflow
Review Existing Internal Solution
Industry & External Research
What's the impact if we take this action to the cohort?
Evaluate Project & Team Fit
Identify Enterprise Partnership
Complete ROI Assessment
Complete Ethical Review – intake form
Method Proposal & Review:
Adoption Potential
Plausibility
Compare Initial Governance and Compliance Standard
Conduct Method Review
Complete Ethical AI & Bias Model Review
Design Experiment
Define Pilot KPIs
Conduct Pilot Analytics Benefit Review
Conduct Pilot Ethical AI & Bias Review (SA-ME)
Draft Key Messaging and Communication
Evaluate Pilot KPIs
Conduct Annual Analytics Benefit Review
Conduct Annual Ethical AI & Bias Review (SA-ME)
Monitor Key Metrics
Conduct Product Retirement Assessment
Document Product for Future Reference
Sunset Development Work
Perform Data Identification
Draft UX/UI Design
Sample Assessment (SA) and Equity Escalation (Compliance/Chief Equity officer)
Perform Data Wrangling
Build Baseline Models and Select Model
Perform Baseline Model Validation
Identify Additional Research Needs & Weight Costs vs Added Benefit
Model Evaluation (ME) and Equity Escalation
Refine Baseline Model
Conduct User Interviews
Develop UX/UI
Build MVP
Perform Pilot Model Validation
Conduct User Trainings
Determine Data Availability & Frequency
Yes
Is All Data in EDW?
No
Design Data Inflow Process
Evaluate Workflow Integration Potential
Propose ETL Process and Production Environment
Evaluate Model Speed & Complexity
Draft Pilot Test Environment and Workflow Integration Plan
Develop Test Environment for Workflow Integration
Deploy Model into Test Environment
Deploy Model to Production
Integrate into Workflow
Generate EDC Documents
Automate Annual Ethical AI & Bias Review
Establish Feedback Loop
Automate Model Validation
Shut down Production Pipeline
Archive Engineering Pipelinefor Future Accessibility
Iterative Process
Data Science Workflow Version 0.1

Our Approach to Responsible AI

Vended Solutions

Proven off-the-shelf solutions

In-House Developed

Improve our internal capabilities and agility

Collaborations

Build community relationships to accelerate learning

Contact


@gregorysnelson


linkedin.com/in/gregorysnelson/


greg.nelson@imail.org


919.931.4736

BREAK

(will start again at 1:25pm EST)

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

AI Showcase Part #2 –
Transparency and Accountability

- FTC
- FDA
- AHRQ
- CDC/NIOSH
- AMA
- Duke-Margolis
- University of California

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

Section 5 of the FTC Act:

Enforcing Truth & Fairness in the Use of AI in Health Technologies

The views expressed in this presentation are my own views and not necessarily the views of the Commission or any individual Commissioner.

Devin Willis
U.S. Federal Trade Commission
Division of Privacy & Identity Protection
January 14, 2022

Be Transparent

Section 5 of the FTC Act

Deceptive or **unfair** acts or practices in or affecting commerce are unlawful.

(15 U.S.C. § 45)

- **Be truthful and don't overpromise capabilities** of health AI
  - Have evidence to support health performance claims
    - *New Consumer Solutions LLC (Mole Detective Apps)* (2015)
  - Have evidence to support claims that product is not biased or can reduce bias or improve decision-making
- **Be truthful and don't misrepresent** the collection, privacy, data security, or use of consumers' personal information
  - *Flo Health Inc.* (2021); *Everalbum, Inc.* (2021); *Facebook* (2019)
- **Disclose material information**. Be transparent about the use of automated tools and why consumers' data are collected or used
  - *CompuCredit Corporation* (2008)

Be Accountable

Section 5 of the FTC Act

Deceptive or **unfair** acts or practices in or affecting commerce are unlawful.

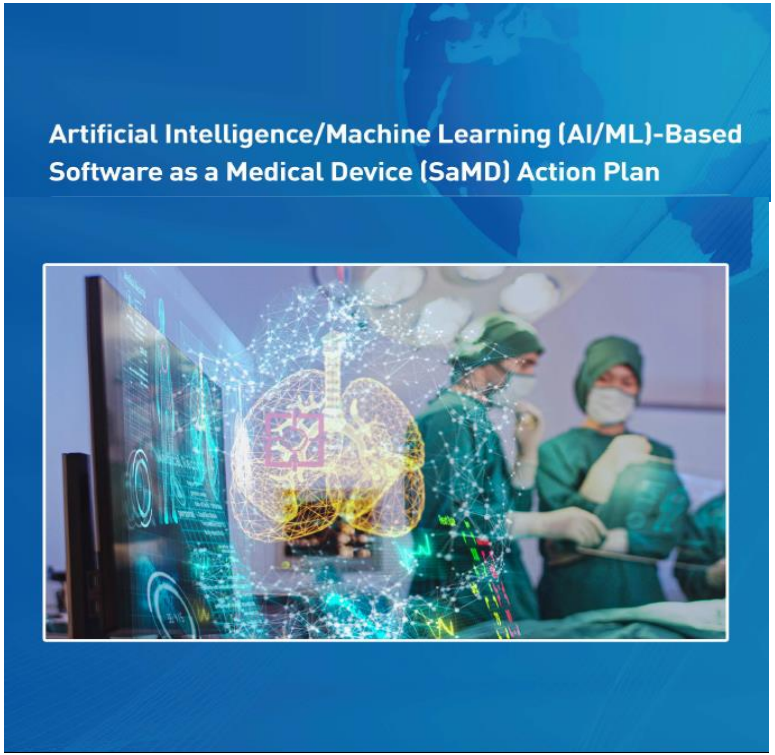
(15 U.S.C. § 45)

- Take **reasonable steps to protect the privacy and security** of sensitive personal information (e.g., sensitive health information)
  - *SkyMed International, Inc.* (2020)
- Take **reasonable steps to ensure that the use of a health AI technology doesn't otherwise cause more harm than benefit**—keep an eye out for well-intended uses that could have unintended consequences
  - FTC PrivacyCon 2020: Ziad Obermeyer's health AI research in *Science*
  - FTC PrivacyCon 2021: *Algorithmic Bias Playbook*, Ziad Obermeyer
  - "Aiming for truth, fairness, and equity in your company's use of AI" (2021 FTC Business Blog)
  - FTC Hearings on Algorithms, Artificial Intelligence, and Predictive Analytics (2018)

Transparency of Artificial Intelligence/Machine Learning (AI/ML)-Enabled Medical Devices

Aubrey Shick
Digital Health Specialist, Center for Devices & Radiological Health (CDRH)
CDRH Digital Health Center of Excellence, US FDA

Tailoring a Regulatory Framework



Published in 2021

Action Plan for AI/ML-Based SaMD

Outlines five next steps to advancing access:

1. Update the proposed AI/ML regulatory framework
2. Strengthen FDA's role in harmonizing GMLP
3. Foster a patient-centered approach
4. Support development of regulatory science methods
5. Advance real-world performance pilots

A Collaborative Approach to AI/ML-Enabled Devices

Recent Milestones

Published AI/ML-SaMD Discussion Paper

First joined Collaborative Community related to AI/ML

Evolving Role of AI in Radiological Imaging

Public Workshop on AI/ML in Radiological Imaging

PEAC Mtg on Patient Trust in AI/ML Devices

Published AI/ML Medical Device Software Action Plan

Posted List of Currently Marketed AI/ML Devices

Transparency of AI/ML-Enabled Medical Devices

Public Workshop on Transparency of AI/ML Devices

Published GMLP Guiding Principles

2019 **2020** **2021**

TRANSPARENCY: Degree to which appropriate information about the device – *including its intended use, development, performance, and, when available, logic* – **is clearly communicated to stakeholders**

**Working definition of Transparency, above, for purposes of this presentation adapted from ISO/IEC JTC1 SC42 WG1 25059 (draft)*

AI/ML-Enabled Medical Devices: Opportunities & Challenges

OPPORTUNITIES

- **Significant positive impact on health care**
  - Earlier disease detection
  - More accurate diagnosis
  - New insights into human physiology
  - Personalized diagnostics and therapeutics
- **Applications across all medical fields**
- **Ability to learn, adapt, and improve performance**

CHALLENGES

- **Fit-for-purpose data sets for development and testing, including diversity**
- **Identification and minimization of bias**
- **Opacity of some algorithms**
- **Providing oversight for an adaptive system**
- **Ensuring transparency to users**

Transparency is Fundamental to a Patient-Centered Approach

Transparency supports the safe and effective use of AI/ML-enabled medical devices.

1. Allows patients, providers, and caregivers to make informed decisions
2. Supports proper use of a device
3. Promotes health equity
4. Facilitates evaluation and monitoring of device performance
5. Fosters trust and promotes adoption

Continuing to Improve Transparency

- What are the needs of specific stakeholders?
- What is the appropriate information to communicate?
- What is the best way to communicate that information?
  - How can device labeling be improved?
  - How can other public-facing information be improved?
  - What else can be done to promote transparency?

We are carefully considering the discussions held in our public workshop on the Transparency of AI/ML-enabled Medical Devices, as well as comments from the public docket to inform our next steps toward improving transparency.



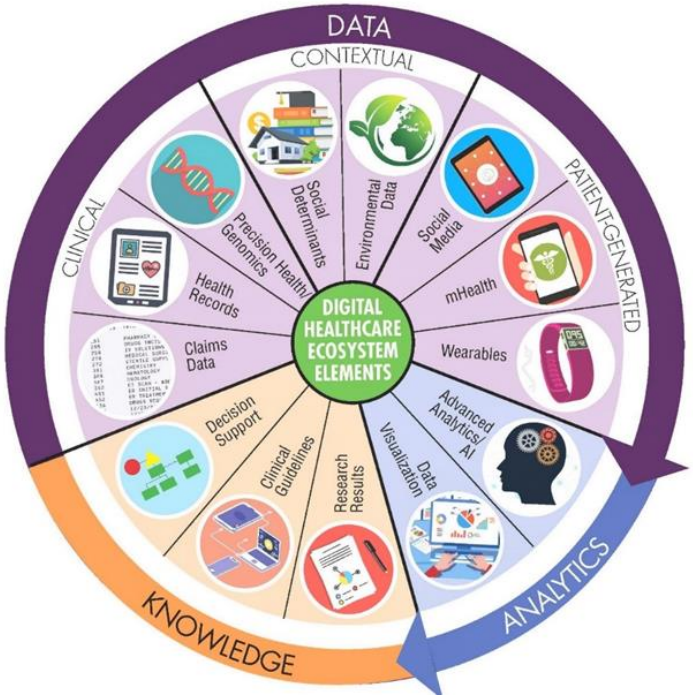
AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ

Supporting the Development of Responsible AI

Chris Dymek, EdD
Director, Digital Healthcare Research Division
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality
January 14, 2022

Digital Healthcare Research (DHR)



DHR's **mission** is to determine how the various components of the ever evolving digital healthcare ecosystem can best come together to positively affect healthcare delivery and create value for patients and their families.

DHR's **vision** is that every patient and care team will have ready access to *all* applicable data and knowledge, mediated by advanced analytics and understandable visualizations, to address a patient's health and healthcare. We are after ultimate data and knowledge liquidity at the point of care.

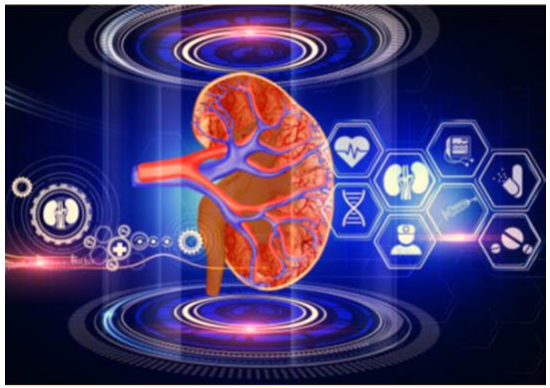
https://digital.ahrq.gov/
https://digital.ahrq.gov/annual-report-2021

Recently Completed AI Research Exemplar

- Anesthesiology Control Tower: Feedback Alerts to Supplement Treatment (ACTFAST)
  - **Using algorithms for real-time monitoring during surgery can predict and prevent adverse outcomes, leading to better outcomes for patients.**
    - Dr. Michael Avidan and a team of researchers and computer scientists at Washington University developed and evaluated an air traffic control-like command center for operating rooms.
    - The study applied data mining and machine learning to develop predictive algorithms, helping to predict patients who are at risk for specific complications, including respiratory failure, kidney failure, and death.

Emerging AI Research Exemplar

- Transforming Kidney Care in the Emergency Department Using Artificial Intelligence-Driven Clinical Decision Support
  - Acute kidney injury (AKI) is a very common condition for patients presenting in the ED but timely diagnosis is difficult due to manifestation delays.
  - Drs. Jeremiah Hinson and Scott Levin and a Johns Hopkins University-based research team are developing an EHR-based algorithm to estimate AKI risk and flag patients at high risk for AKI. This algorithm will then be translated into an AKI-CDS system and pilot-tested among emergency department providers.



Contact Info

Christine.Dymek@ahrq.hhs.gov

Artificial Intelligence and OSH:
Opportunities and Risks

Jay Vietas, PhD, CIH, CSP

Chief, Emerging Technology Branch

14 January 2022

The National Institute for Occupational Safety and Health

The U.S. Federal agency responsible for *conducting research* and *making recommendations* for the prevention of work-related injury and illness.

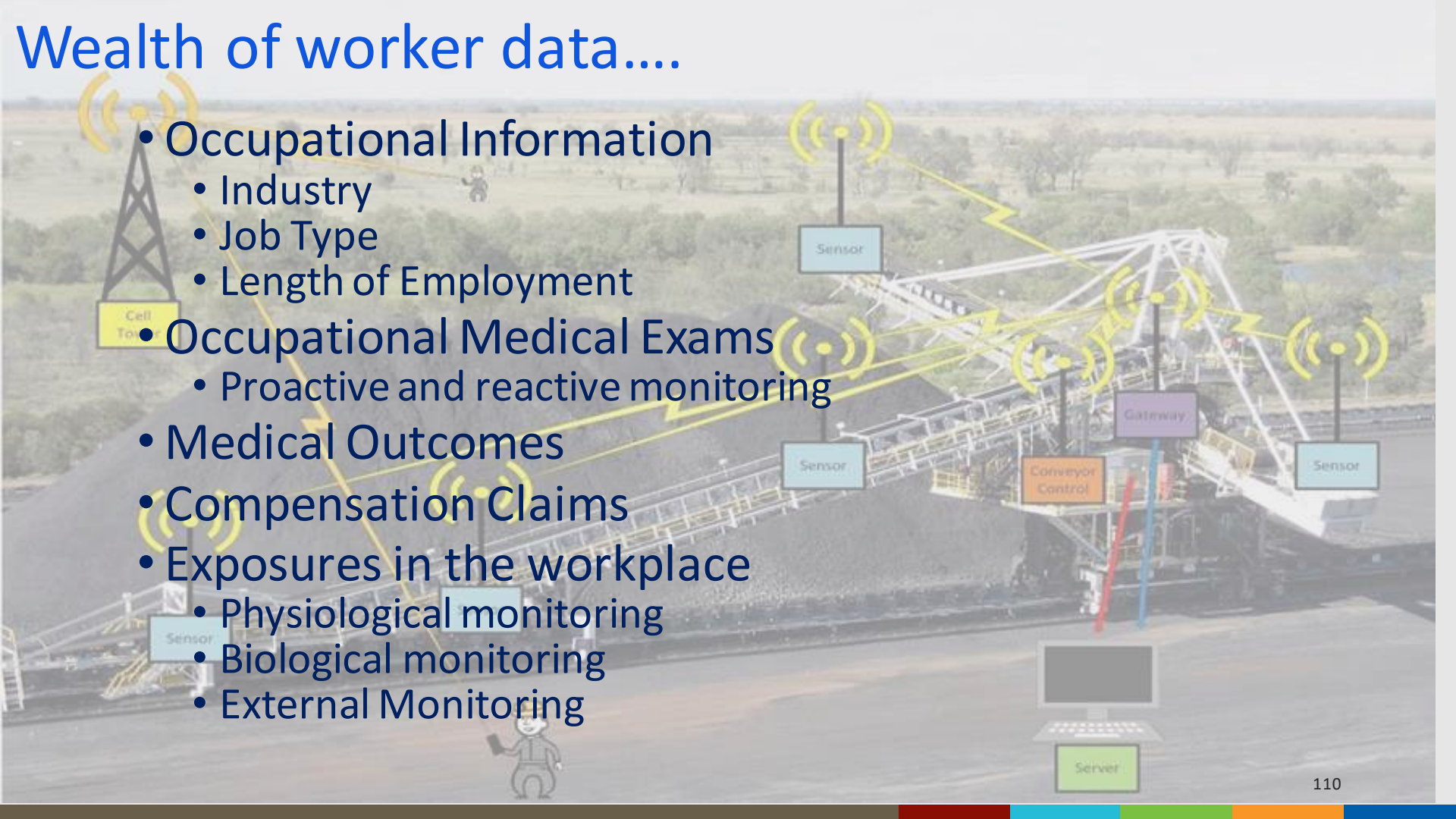
Mission: To *develop new knowledge* in the field of occupational safety and health and to *transfer that knowledge into practice*.

Work: A Social Determinant of Health

- 2.7M occupational injuries/illnesses/yr*
- Work rarely guides clinical decision-making
- Work information incomplete and inconsistent

Wealth of worker data….

- Occupational Information
  - Industry
  - Job Type
  - Length of Employment
- Occupational Medical Exams
  - Proactive and reactive monitoring
- Medical Outcomes
- Compensation Claims
- Exposures in the workplace
  - Physiological monitoring
  - Biological monitoring
  - External Monitoring



IOM: Benefit of Work information in EHR

- Care (quality, safety, efficiency, coordination)
- Treatment
- Return to Work
- Health Disparities

➢ Occupational Data for Health: Tips for Health IT System

  - https://www.cdc.gov/niosh/docs/2022-101/default.html

Adapted from Getty Images

Challenge: Collecting the data we need…

- System to meet needs of all
- Interoperability
- Data privacy and security
- Meet regulatory requirements

Adapted from Getty Images

Opportunities through AI:

- **Current**:
  - WC Claims: narrative to assign standard codes
  - NIOCCS: narrative data and put into standard federal codes
- **Future**: Improved….
  - Understanding of chronic disease risk/development
  - Understanding of impact of work on mental health
  - Definition of healthy workplace

Adapted from GettyImages

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

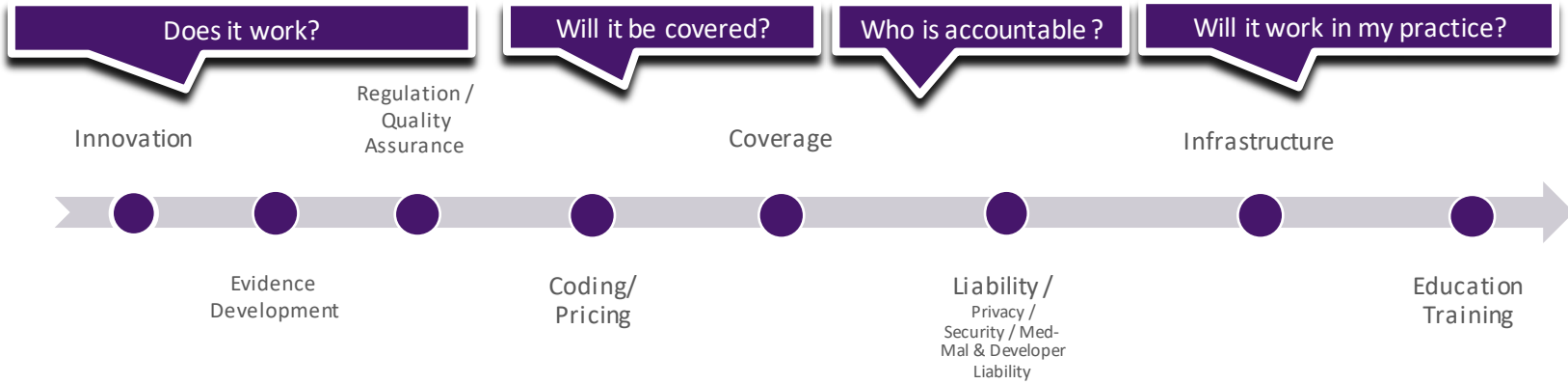
Physician Perspectives on Transparency in Augmented Intelligence (AI)

Jack Resneck Jr., MD

President-Elect, American Medial Association
Vice Chair, Dermatology, University of California – San Francisco

Transparency: A Precondition for Clinical Integration

From innovation to clinical integration . . . AI considerations



Equity

Evidence

Ethics

Physician Perspectives: AI Transparency

- AMA convened experts from across the Federation of Medicine to better understand the profession's perspectives and concerns related to augmented intelligence (AI) product transparency and explainability
  - Radiology, cardiology, ophthalmology, pathology, surgery, dermatology, internal medicine
- **Perspective: AI done right can improve outcomes**
- **Concern: Lack of transparency threatens trust**
  - Development – how were tools designed, validated and in which populations?
  - Data Quality - Inaccurate or mislabeled data threaten performance and trust
  - Bias – Do the data sets used to develop, test and validate the AI span diverse ethnic and racial populations? How limited or generalizable are the AI outputs?

Transparency ⟶ Explainability

- Explainability is a key element of physician trust in AI products
  - Additional transparency may be required to ensure black box algorithms are explainable
- Physicians need to be able to answer key questions:
  - How does it learn?
  - What decisions is it making?
  - What does the result mean?
  - How will I know when it's "gone wrong?"

AI Product Labeling

- Product labeling for AI products should be robust and require new product disclosures to help build physician trust and understanding of the product
- FDA and stakeholder communities need to work to develop a list of required disclosures
    - Required disclosures should include information about:
        - What safety and efficacy data has shown about the product in question and whether clinical studies have been conducted
        - The populations for which the product has been validated
        - The potential limitations of the data sets used in developing AI products
        - Elements helping explain algorithm decision making/logic (explainability)
        - Information on the use of an individual's data to develop and/or train AI
- Post-market surveillance requirements are critical

Physicians' powerful ally in patient care

Building Equitable and Trustworthy AI

Christina Silcox, PhD
Digital Health Policy Fellow

ONC AI in Health IT Showcase
January 14, 2022

AI in Health

Figure 2: Framework of all AI Use Cases in Healthcare

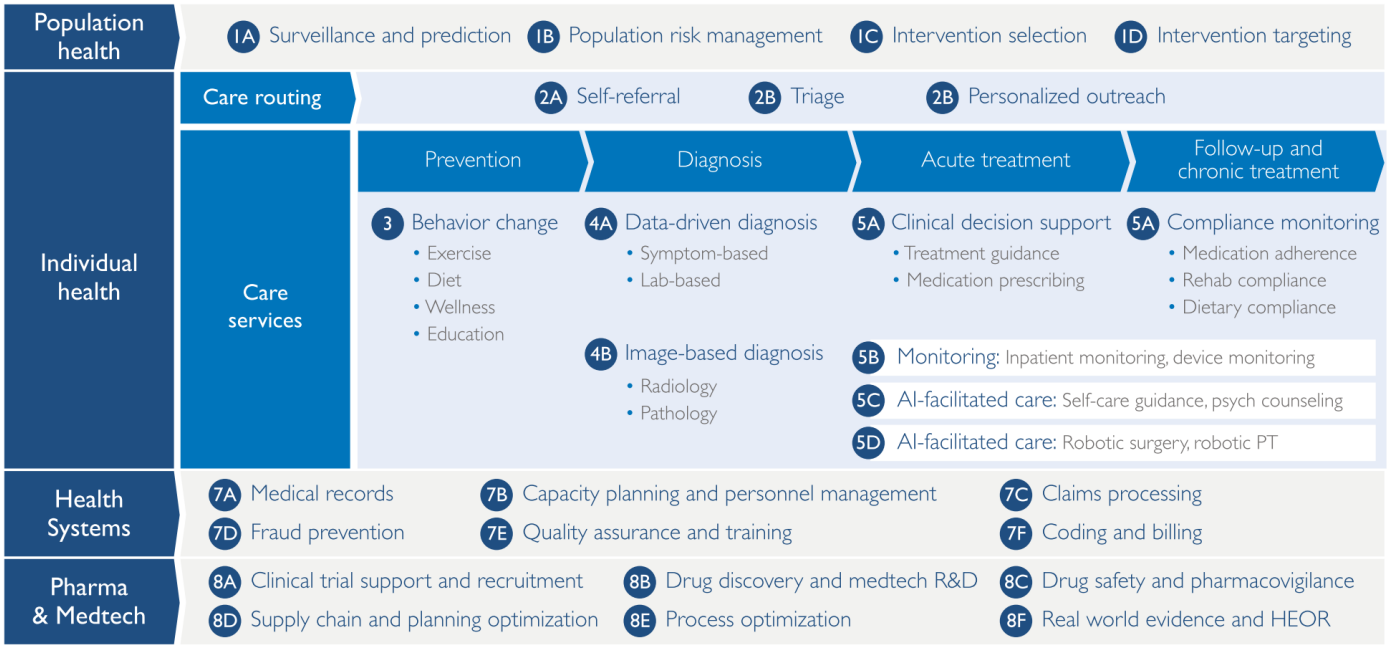


Figure from USAID's "*Artificial Intelligence in Global Health: Defining a Collective Path Forward*" https://www.usaid.gov/cii/ai-in-global-health

Duke-Margolis AI Papers

Coming Soon!

- Accessibility of RWD for post-market evaluation of AI-enabled software
- Understanding Bias and Fairness in AI-enabled Healthcare Software
- How Health Systems Decide to Use Artificial Intelligence for Clinical Decision Support

What do stakeholders want to know?

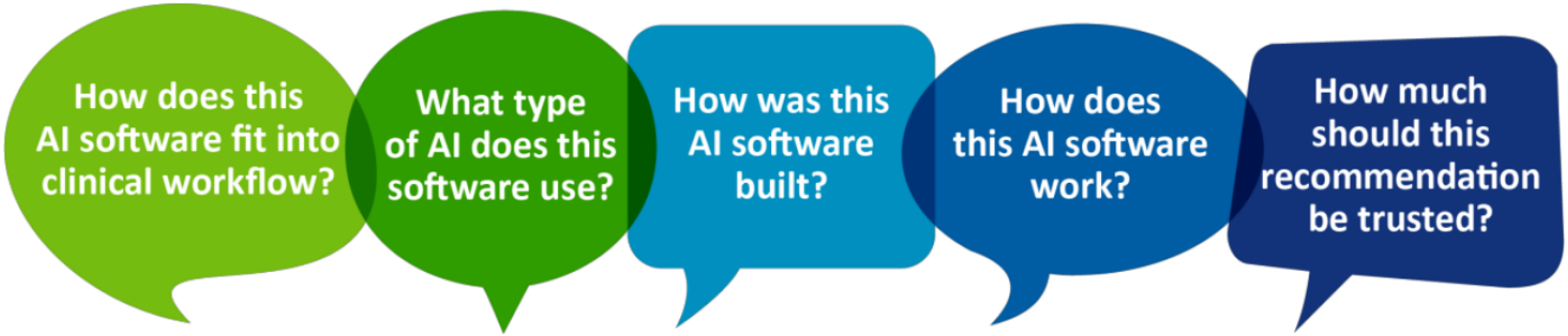
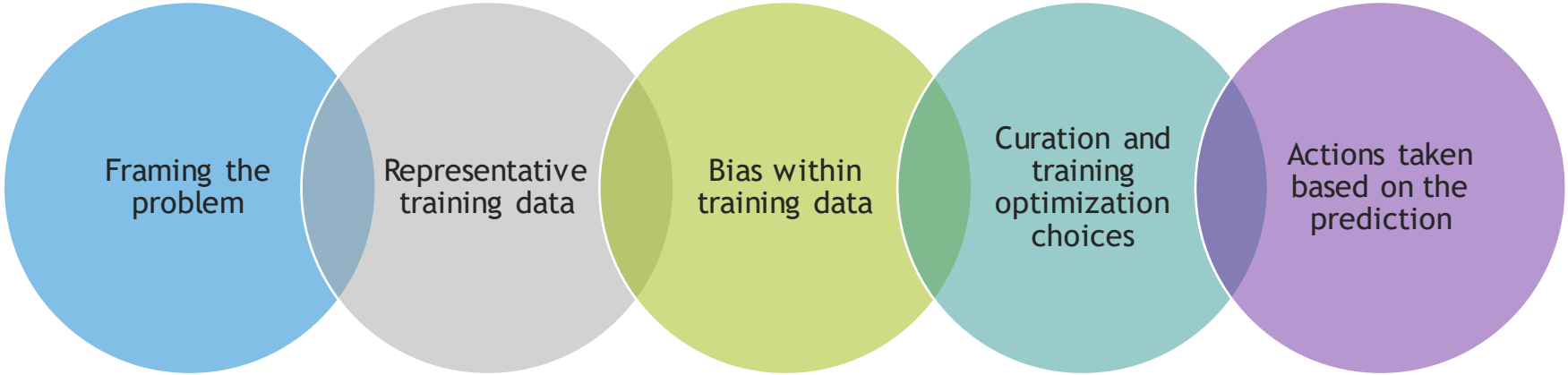


Figure 3. Categories of information for AI-Enabled Clinical Decision Software. *Various stakeholders throughout the total product lifecycle of a software product will want specific information of what the software does and how it fits into the workflow, what type of AI is used and how it was built, as well as information about how it works and when to trust the results.*

Why are we worried about "trustworthy" AI?

- It's new!
- AI is built on health data, and health data is heterogeneous, complex, fast-changing, and of variable quality
- Less information about how the product was made and "how it works"
- Faster update cycles
- Privacy
- Concerns about bias

How does AI become biased or unfair?



Recommendations

- Trustworthy products should:
  - Show performance data on an independent test set, and separate out performance among key subgroups
  - In real-time, give information regarding the certainty of the recommendations and (when possible) show the key factors that caused the prediction/recommendation
  - Publicly disclose at least summary information about the training data and process, including the patient population used
  - Clearly indicate intended use (such as the purpose, user, significance of decision, level of autonomy given, patient populati on) to all users
- Data quality is critical to trustworthy and equitable AI-enabled products
  - Manufacturers need to clearly define data input requirements, including the structure and definition of each data element
  - Health systems need to work to improve data quality and better understand, document, and mitigate bias within health data
- Health care systems need to be more open about their internal process challenges and informational needs so manufacturers can develop products that solve real problems in ways that fit into existing work flows (or make the case that workflows should change!)
- Manufacturers and health systems should work together to monitor system performance after implementation, and share information about product limitations, bias, and adverse or near-miss events.

Operationalizing Principles for the Responsible Use of AI in Healthcare

Cora Han, Chief Health Data Officer, University of California Health

ONC AI in Health IT Showcase, January 14, 2022

UNIVERSITY OF CALIFORNIA
HEALTH

University of California Working Group on Artificial Intelligence

UC Responsible AI Principles

- Appropriateness
- Transparency
- Accuracy, Reliability, and Safety
- Fairness and Non-Discrimination
- Privacy and Security
- Human Values
- Shared Benefit and Prosperity
- Accountability

Operationalizing the UC Responsible AI Principles

- Risk and Impact Assessment Framework
- Documentation
- Human Review and Monitoring
- Representation and Engagement
- Training and Educational Programs
- Procurement Best Practices
- Further Research

BREAK

(will start again at 2:35pm EST)

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

AI Showcase Part #3 –
Evaluating Data Input Needs & Real-World Performance

- White House OSTP
- House Ways and Means Committee
- FDA
- HRSA / AllianceChicago
- Wellsheet
- Mayo Clinic
- Olive
- The Data Nutrition Project
- The Omega Concern
- Siemens Healthineers

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

Human Discretion and Assumptions in AI Development

Rashida Richardson

Senior Policy Advisor for Data and Democracy

White House Office of Science and Technology Policy

Healthcare AI must be designed with a nuanced understand of our society and the healthcare sector

- This can include:
  - Challenging or interrogating assumptions about the drivers of certain healthcare system problems or challenges certain patient populations face.
  - Consideration of societal inequities or challenges, such as the digital divide or barriers to transportation.
  - Consultation with end-users and potentially affected patient populations

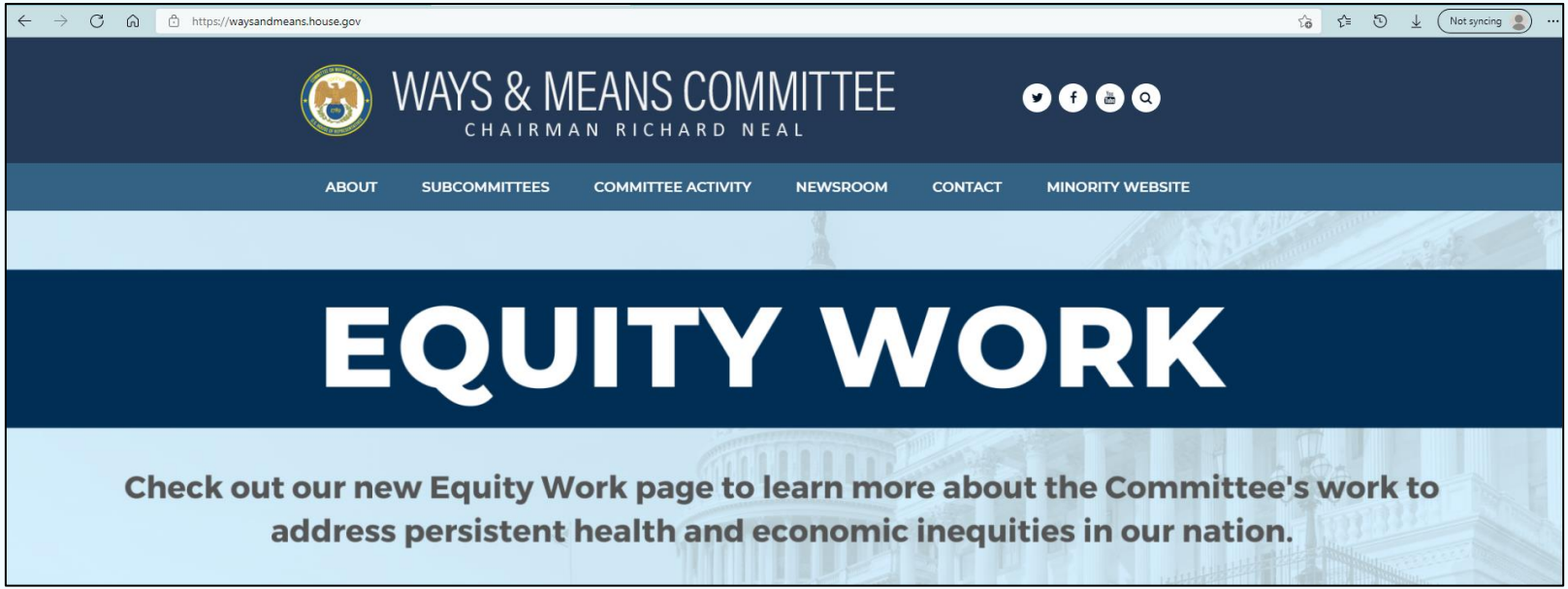
- In November 2021 OSTP co-hosted a series of six public events to engage the American public in the policy planning process for a Bill of Rights for an Automated Society. Recordings of the public events are available online.

- The event on AI and the Healthcare System included a moderated panel discussion with clinicians and researchers that explored how human discretion and assumptions can impact AI model design and outcomes.

- The panel highlighted how AI design choices can appear neutral but lead to biased outcomes because they are based on flawed decisions or misguided assumptions.

Fact versus Fiction: Clinical Decision Support Tools And The (Mis)use Of Race

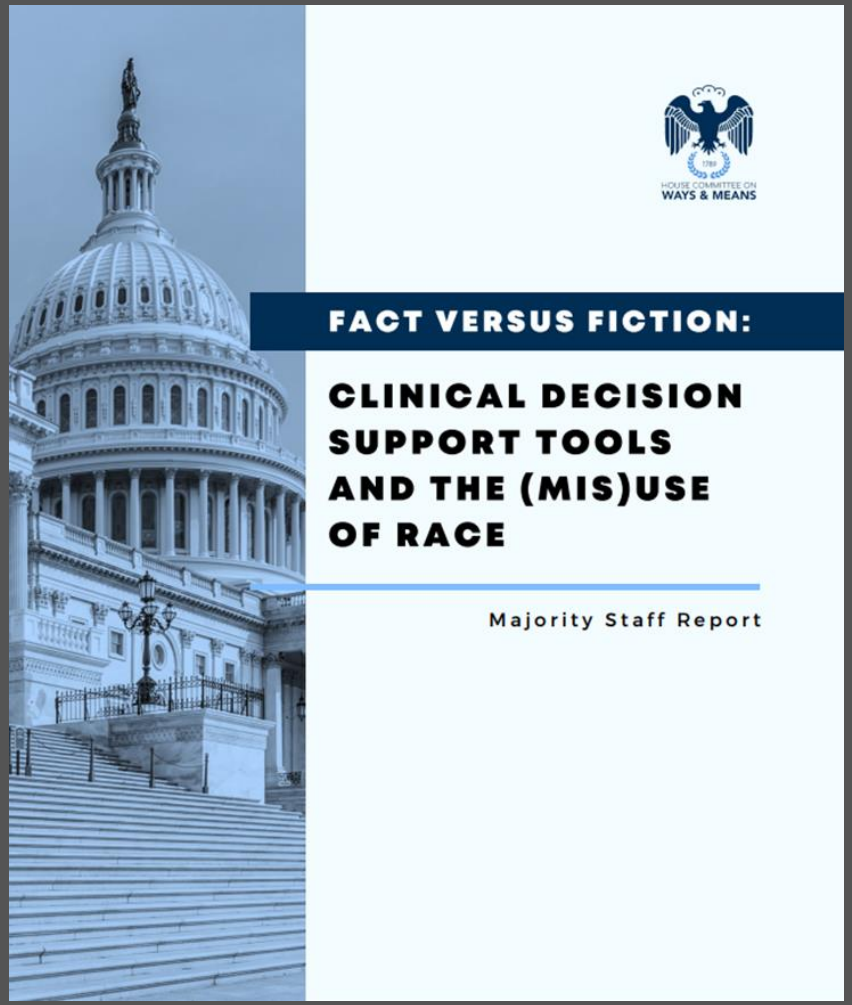
Rachel Dolin, PhD
Professional Staff
Committee on Ways and Means, Majority



Committee On Ways And Means Website

https://waysandmeans.house.gov/

Report On Clinical Decision Support Tools (CDSTs)



Background

- Evolving technology is continually impacting the delivery of health care
- ***Clinical Decision Support Tools (CDSTs)*** incorporate evidence-based medicine and patient characteristics to make care decisions
  - Guide screening, diagnosis, and treatment of patients
  - Most sophisticated versions are clinical algorithms, which incorporate inferential intelligence to predict patient outcomes
- While there are benefits to using CDSTs, in June 2020, the *New England Journal of Medicine* highlighted the potential for racial bias and harm in using modifiers for race
- In response to these findings, in September 2020, Ways and Means Chairman Richard E. Neal sent out targeted letters to professional medical societies and a Request for Information (RFI) to a broad group of health care stakeholders

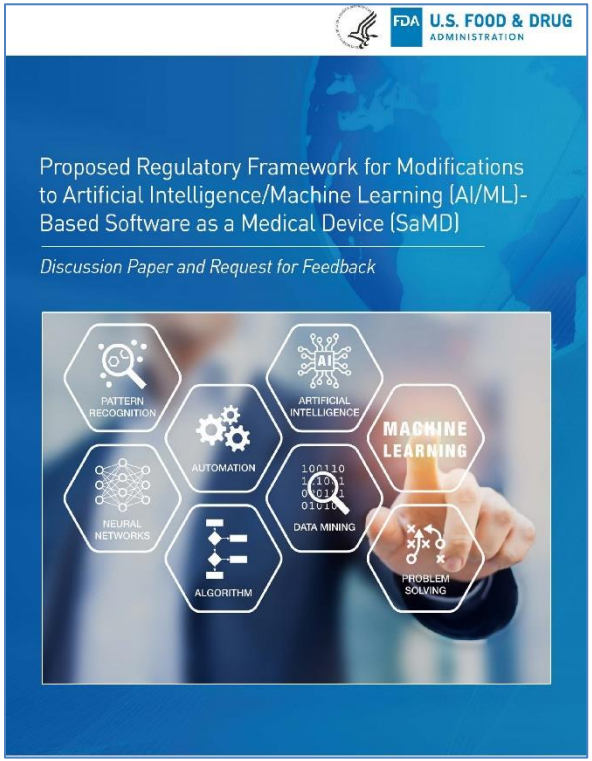
Key Findings

- Respondents acknowledged the unacceptable nature of findings that CDSTs produce avoidable differences for patients of color
  - One-third of respondents said they are not planning to reevaluate use of race and ethnicity in clinical algorithms
- Raised the absence of a central hub of accountability as a barrier to addressing these complex issues across scientific and medical professions
  - Some recommended leadership from largest and most influential organizations (e.g., the Centers for Medicare & Medicaid Services) must assemble stakeholders to develop standards, guidance, and best practices for using race in CDSTs.
- Emphasized role of bias in CDST development and care delivery, suggesting solution lies upstream (e.g., at the level of health technology research and development and through clinician education)
- Strategies must be enacted to proactively correct and confront the challenges of the misuse of race and ethnicity in CDSTs

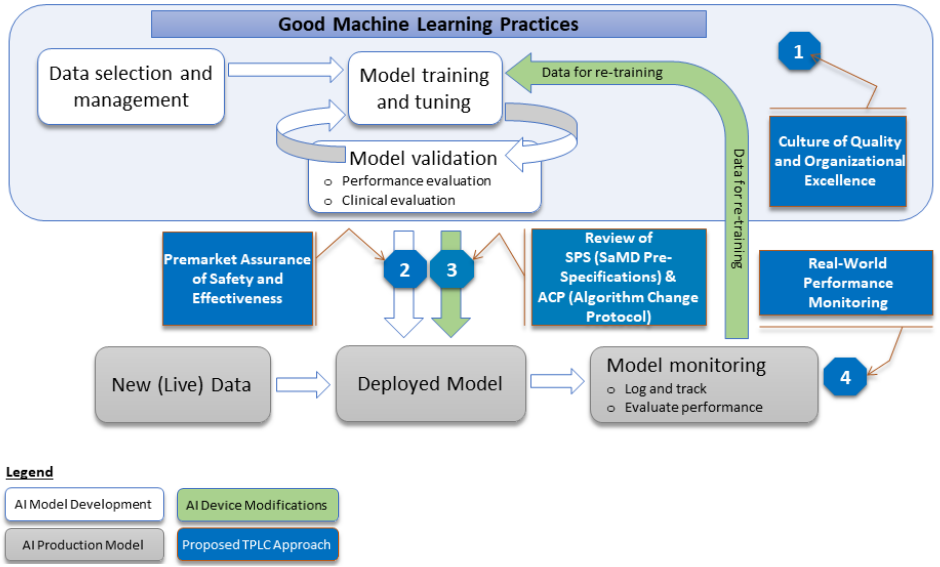
Good Machine Learning Practices and Real World Performance for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Medical Devices

Shawn Forrest, MS
Digital Health Specialist, Center for Devices & Radiological Health (CDRH)
CDRH Digital Health Center of Excellence, US FDA

Proposed Regulatory Framework for AI/ML-Enabled Device Software

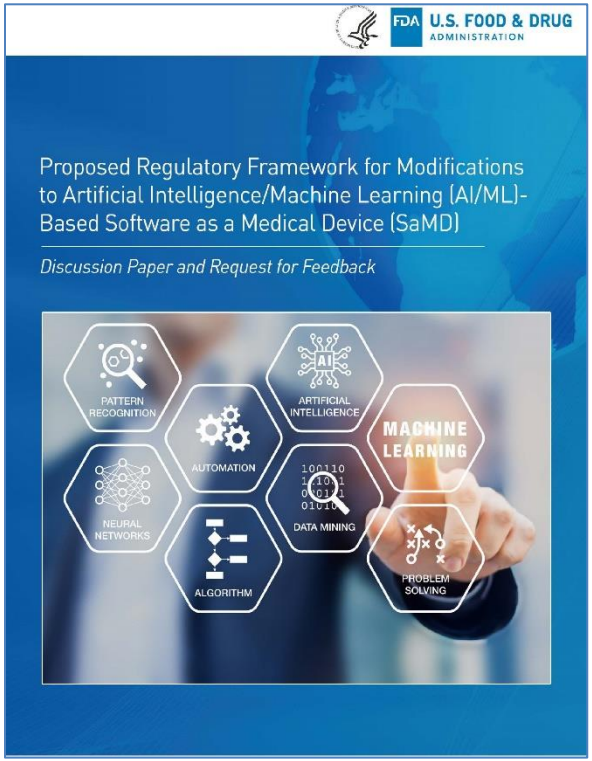


Overlay of FDA's TPLC Approach on AI/ML Workflow



Proposed Regulatory Framework for AI/ML-Enabled Device Software

Gathering Stakeholder Feedback



Since publishing in April 2019 FDA's **Proposed Regulatory Framework for Modifications to AI/ML-Based SaMD**, we've received stakeholder feedback through:

- > 1,000 comments on public docket from a diverse community of stakeholders
- > 30 publications in peer-reviewed journals
- Public Workshops on the Evolving Role of AI in Radiological Imaging (Feb 2020) and Transparency of AI/ML-Enabled Devices (Oct 2021)
- Patient Engagement Advisory Committee (PEAC) Meeting (October 2020)
- Pre-submission meetings on AI/ML devices

A Collaborative Approach to AI/ML-Enabled Devices

Recent Milestones

Published AI/ML-SaMD Discussion Paper

First joined Collaborative Community related to AI/ML

Evolving Role of AI in Radiological Imaging

Public Workshop on AI/ML in Radiological Imaging

PEAC Mtg on Patient Trust in AI/ML Devices

Published AI/ML Medical Device Software Action Plan

Posted List of Currently Marketed AI/ML Devices

Transparency of AI/ML-Enabled Medical Devices

Public Workshop on Transparency of AI/ML Devices

Published GMLP Guiding Principles

2019 **2020** **2021**

Future Plans (2022+) AI/ML Medical Device Software Action Plan

- ❑ Update the proposed AI/ML framework
- ❑ Strengthen FDA's role in harmonizing GMLP
- ❑ Foster a patient-centered approach
- ❑ Support development of regulatory science methods
- ❑ Advance real-world performance pilots

Stakeholder Feedback on AI/ML Approach

What we heard from stakeholders:

1. **Regulatory Framework**: Requested further development of proposed regulatory framework for AI/ML-based SaMD
2. **Good Machine Learning Practices (GMLP)**: Supported the idea of GMLP and the need for harmonization of its efforts
3. **Transparency**: Asked for further discussion with FDA on how these technologies interact with people, including transparency to users
4. **Regulatory Science**: Described need for improved methods related to algorithmic bias and robustness.
5. **Real-World Performance (RWP)**: Sought clarity on RWP monitoring for AI/ML software.

Stakeholder Feedback on AI/ML Approach

What we heard, and what we'll do

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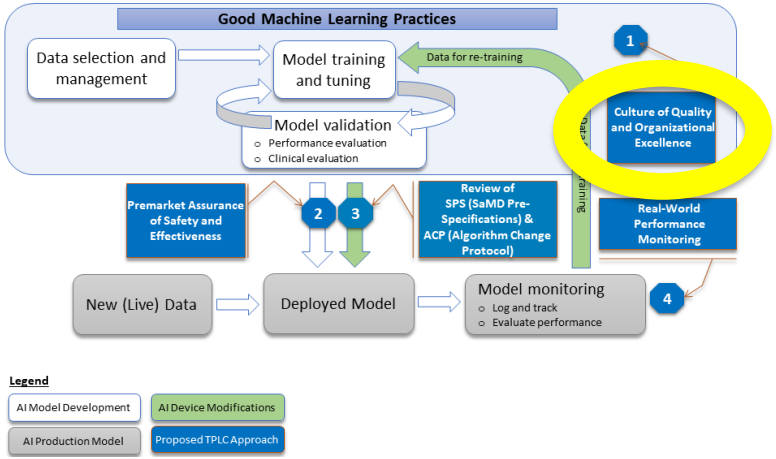
What we'll do -- The AI/ML Action Plan:

1. **Update the proposed AI/ML framework**, including through Guidance
2. **Strengthen FDA's role in harmonizing GMLP** through standards development & other initiatives
3. **Foster a patient-centered approach**, starting with a workshop on transparency to users
4. **Support development of regulatory science methods** related to algorithm bias and robustness
5. **Advance real-world performance pilots** in coordination with stakeholders and other programs

Good Machine Learning Practice (GMLP)

- Accepted practices in ML/AI algorithm design, development, training, and testing that facilitate the quality development and assessment of ML/AI-enabled devices
- Based on concepts from quality systems, software reliability, machine learning, and data analysis



Overlay of FDA's TPLC approach on AI/ML workflow

Adapted from Proposed Regulatory Framework for Artificial Intelligence/Machine Learning (AI/ML)-Based SaMD

Good Machine Learning Practice (GMLP)

- Standards Development:
  - IEEE AI Medical Device Working Group P2801
  - ISO/IEC SubCommittee on AI 42 (ISO/ IEC JTC 1/SC 42)
  - AAMI/ BSI Initiative on AI in Medical Technology
- Collaborative Communities:
  - Xavier AI World Consortium Collaborative Community
  - Collaborative Community on Ophthalmic Imaging
  - Pathology Innovation Collaborative Community
- Other Collaborations:
  - IMDRF AI Medical Devices WG

XAVIER HEALTH

Xavier AI World Consortium Collaborative Community

CCOI

Collaborative Community on Ophthalmic Imaging

Pathology Innovation Collaborative Community Plcc

Pathology Innovation Collaborative Community

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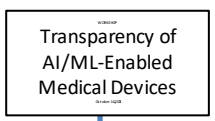
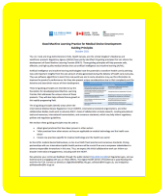


Public Workshop on Transparency of AI/ML Devices



Published GMLP Guiding Principles

2021

U.S. FOOD & DRUG ADMINISTRATION | Health Canada Santé Canada | Medicines & Healthcare products Regulatory Agency

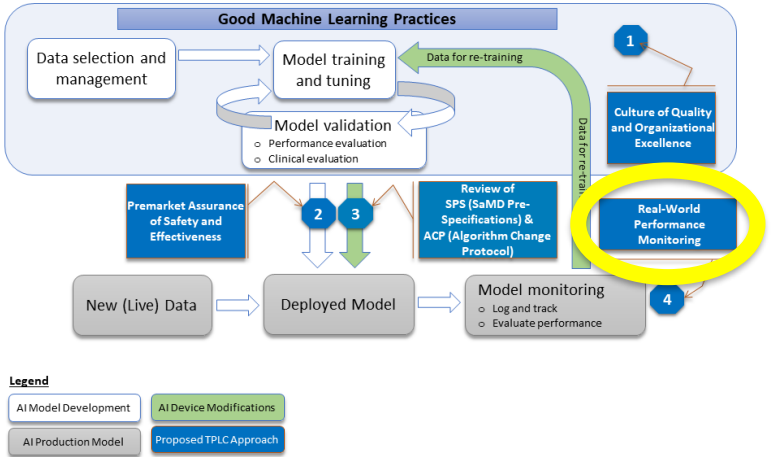
Good Machine Learning Practice for Medical Device Development: Guiding Principles	
Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle	Good Software Engineering and Security Practices Are Implemented
Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population	Training Data Sets Are Independent of Test Sets
Selected Reference Datasets Are Based Upon Best Available Methods	Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device
Focus Is Placed on the Performance of the Human-AI Team	Testing Demonstrates Device Performance During Clinically Relevant Conditions
Users Are Provided Clear, Essential Information	Deployed Models Are Monitored for Performance and Re-training Risks are Managed

https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

Real World Performance

- Collection and monitoring of real-world data will support a total product lifecycle (TPLC) approach to the oversight of AI/ML-enabled software

- By gathering data on real-world use and performance of software, manufacturers can:
  - Improve their understanding of how their products are being used
  - Identify opportunities for improvements, and
  - Respond proactively to safety or usability concerns

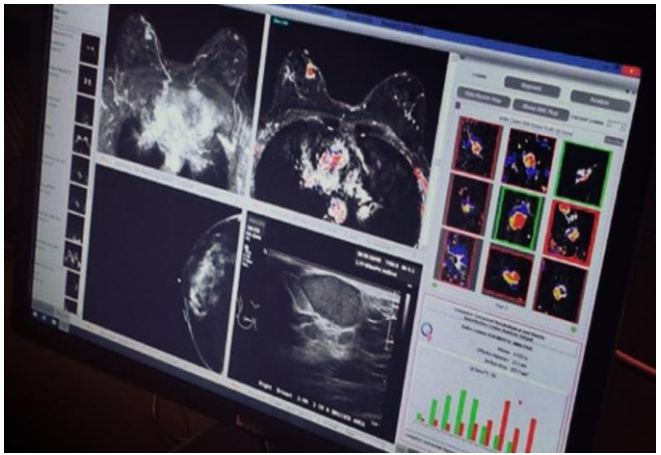


Overlay of FDA's TPLC approach on AI/ML workflow
Adapted from Proposed Regulatory Framework for Artificial Intelligence/Machine Learning (AI/ML)-Based SaMD

Real World Performance

Actions:

- Support the piloting of real-world performance monitoring by working with stakeholders on a voluntary basis
- Coordination with other ongoing FDA programs focused on the use of real-world data
- Develop a framework for seamless gathering, validation, and evaluation of relevant real-world performance metrics
- Continued stakeholder and public engagement



https://angel.co/quantitative-insights

Further Questions or Feedback:

www.fda.gov/digitalhealth

DigitalHealth@fda.hhs.gov

Shawn Forrest, MS

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Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration
shawn.forrest@fda.hhs.gov
(301) 796-5554

HRSA
Health Resources & Services Administration

Multisector Data and Predictive Analytics in Community Health

An ONC Artificial Intelligence Showcase – Seizing the Opportunities and Managing the Risks of Use of AI in Health IT

LCDR Janel Parham, MS, BSN, RN
Health IT/HCCN Team Lead

Candace Webb, MPH
Public Health Analyst
Bureau of Primary Health Care

January 14, 2022

Andrew Hamilton, RN, MS
Chief Informatics Officer

Nivedita Mohanty, MD
Chief Research Officer
AllianceChicago

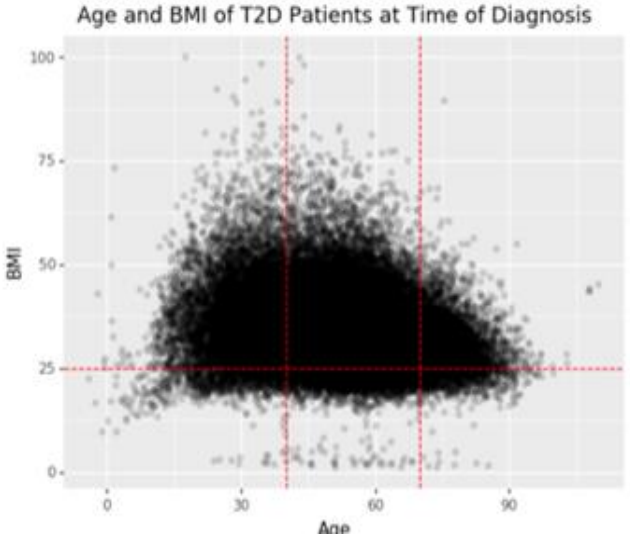
Vision: Healthy Communities, Healthy People

Multisector Data and Predictive Analytics in Community Health

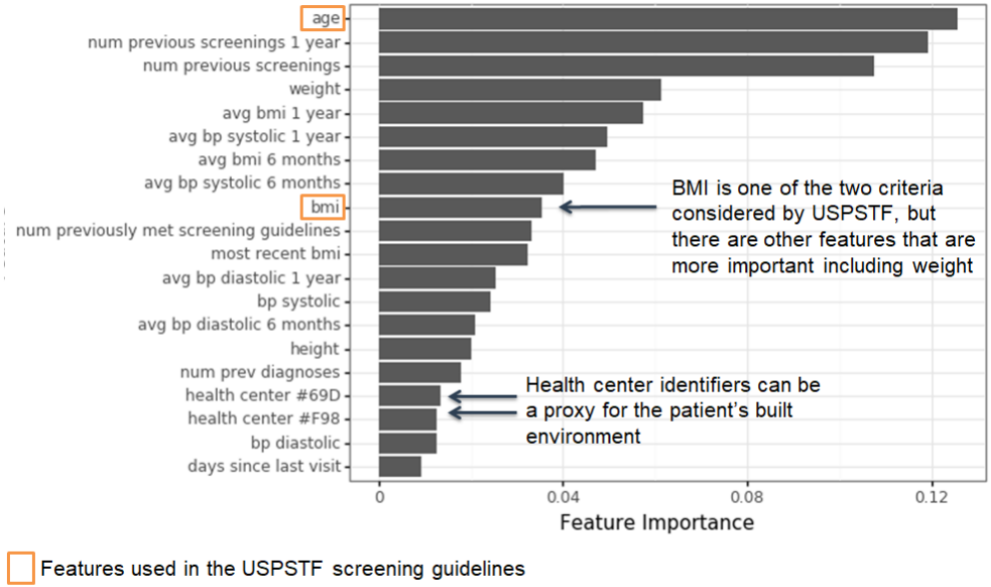
Nivedita Mohanty, MD
Chief Research Officer
AllianceChicago

AllianceChicago
Innovating for better health

Diabetes Risk Prediction: Traditional vs. AI Approach



- 40-70 years old
- BMI ≥ 25



Opportunity: A tool for clinicians to identify patients at risk of developing diabetes using a personalized approach.

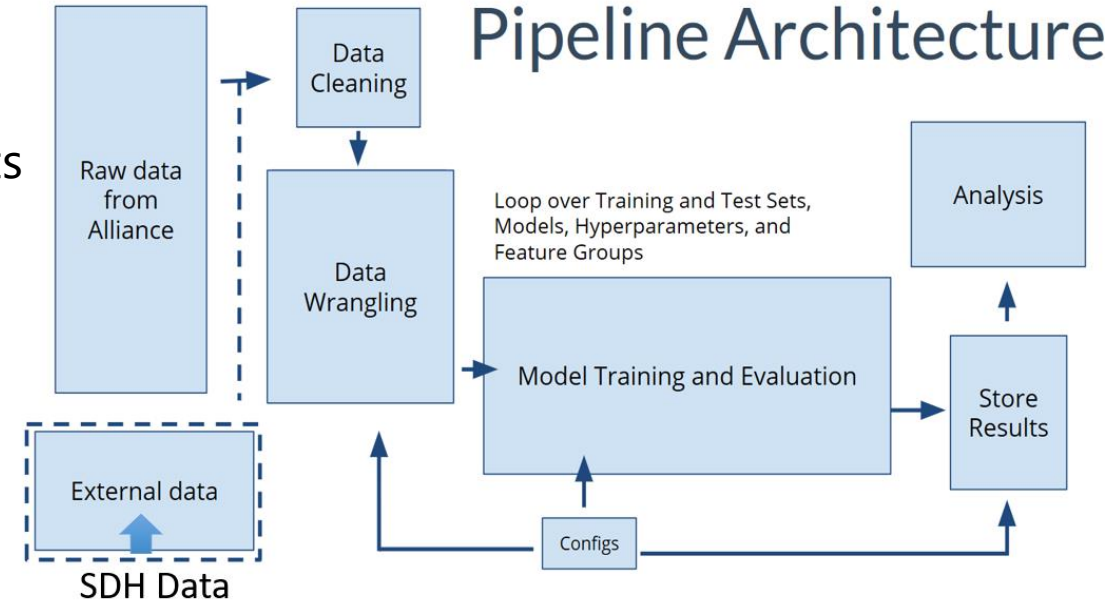
Data Science for Social Good
Summer Fellowship

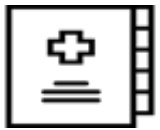
THE UNIVERSITY OF CHICAGO

AllianceChicago

Diabetes Risk Prediction: Traditional vs. AI Approach

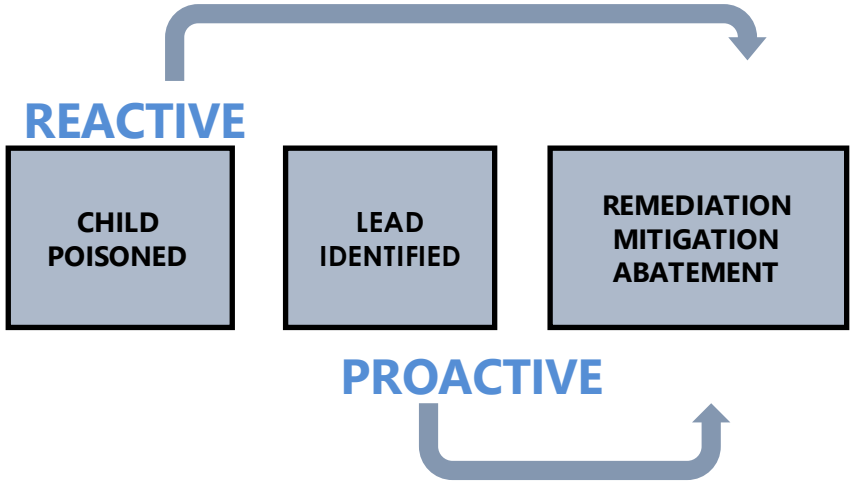
- 1.1 million patients
- 24 health centers
- ~ 8 million visits

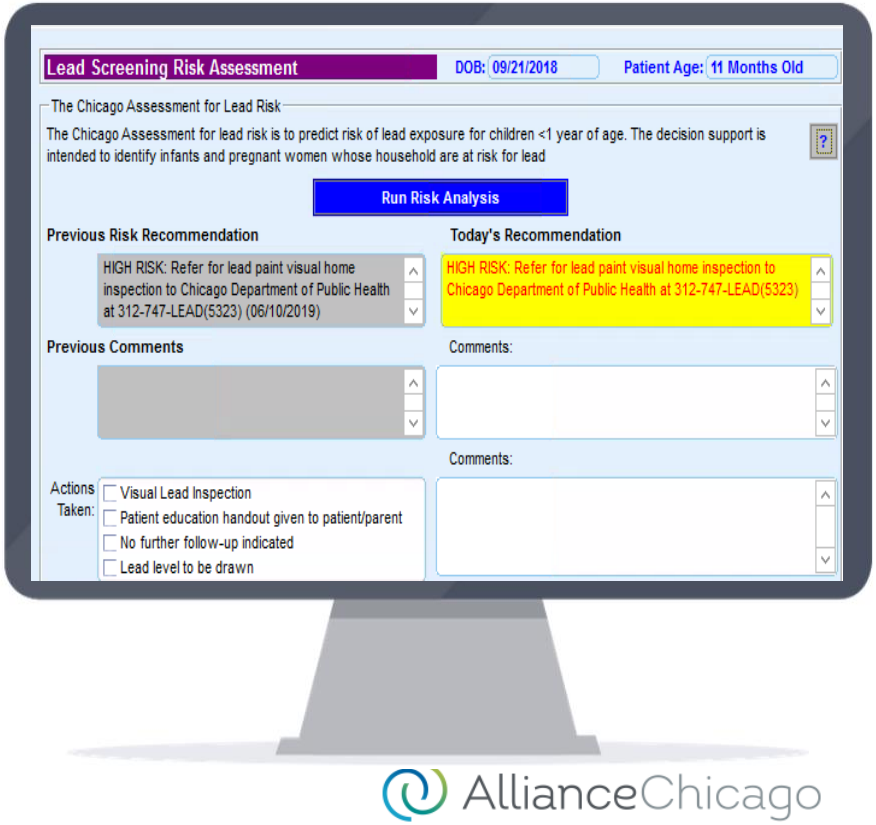




Lead Safe: Proactive Lead Risk Identification

Opportunity: Proactive EHR Clinical Decision Support that Identifies Lead Risk and Facilitates Early Remediation





HEALTHY CHICAGO
CHICAGO DEPARTMENT OF PUBLIC HEALTH

THE UNIVERSITY OF CHICAGO
THE HARRIS SCHOOL
Computation Institute

CITY OF CHICAGO INCORPORATED 4th MARCH 1837

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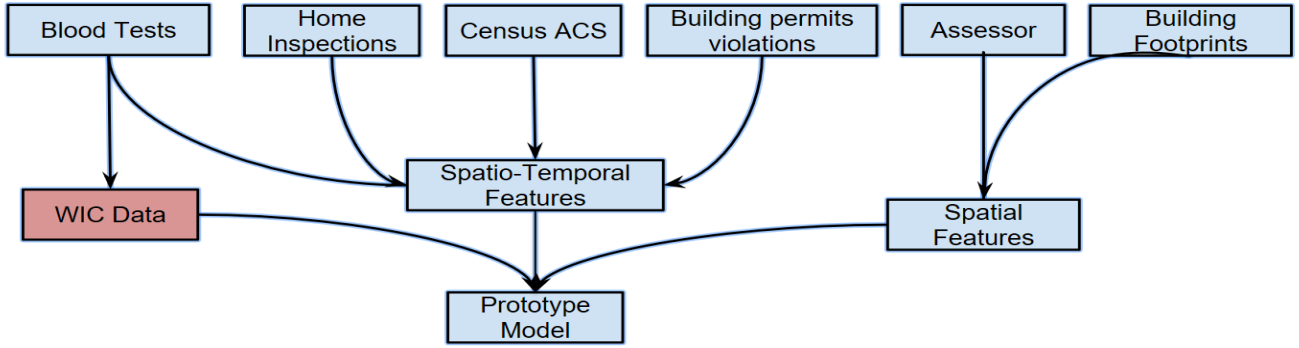
Lead Safe: Proactive Lead Risk Identification



AllianceChicago

THANK YOU!

nmohanty@alliancechicago.org

www.alliancechicago.org/hre

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Wellsheet

Using AI to Transform the EHR Experience with Better Decision Support Tools

Dr. Fred Rachman, CEO
AllianceChicago

Craig Limoli, CEO and Founder
Wellsheet

Wellsheet + AllianceChicago

Innovating for better health

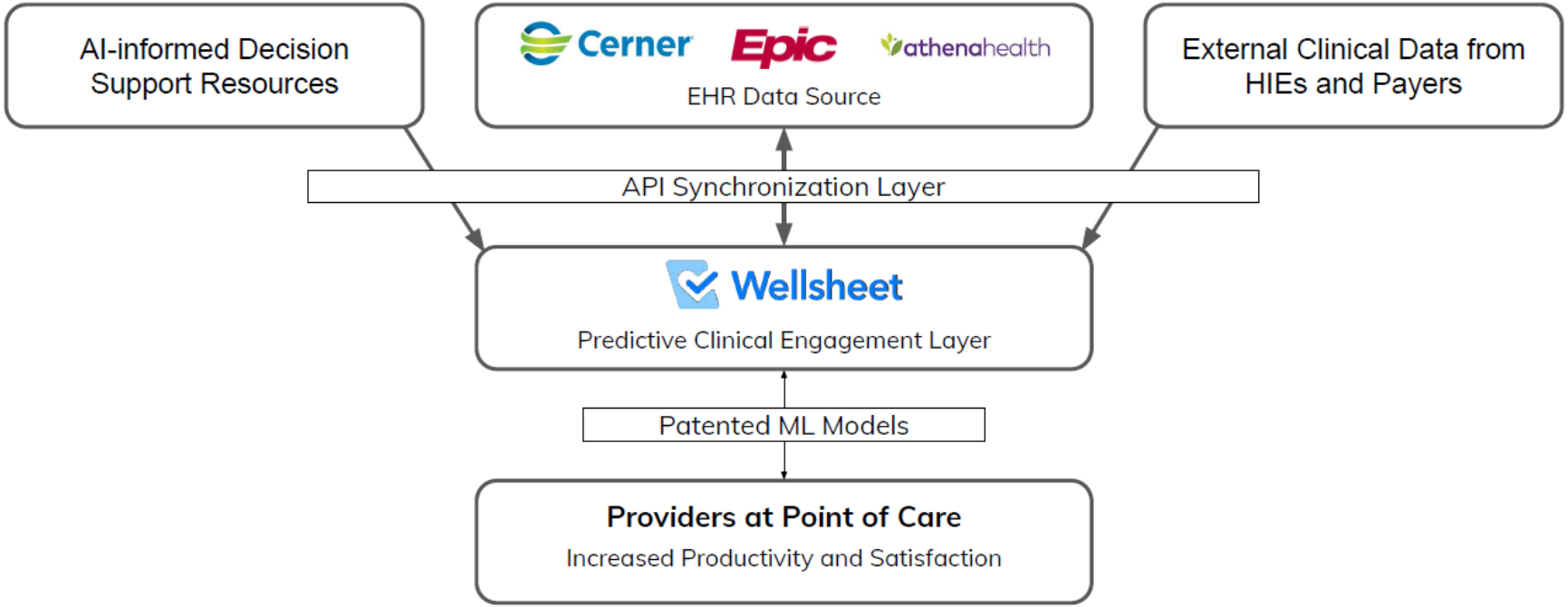
Support AC's clinicians to continue to more efficiently organize information to support clinical care

Leverage interoperable national CDS artifacts to promote adherence to national guidelines

Opportunity to extend across athenaOne and Epic

Incorporate data from broader data sources beyond the EHR including SDOH context to populate AI algorithms

AI Can Transform the Clinician Experience with the EHR

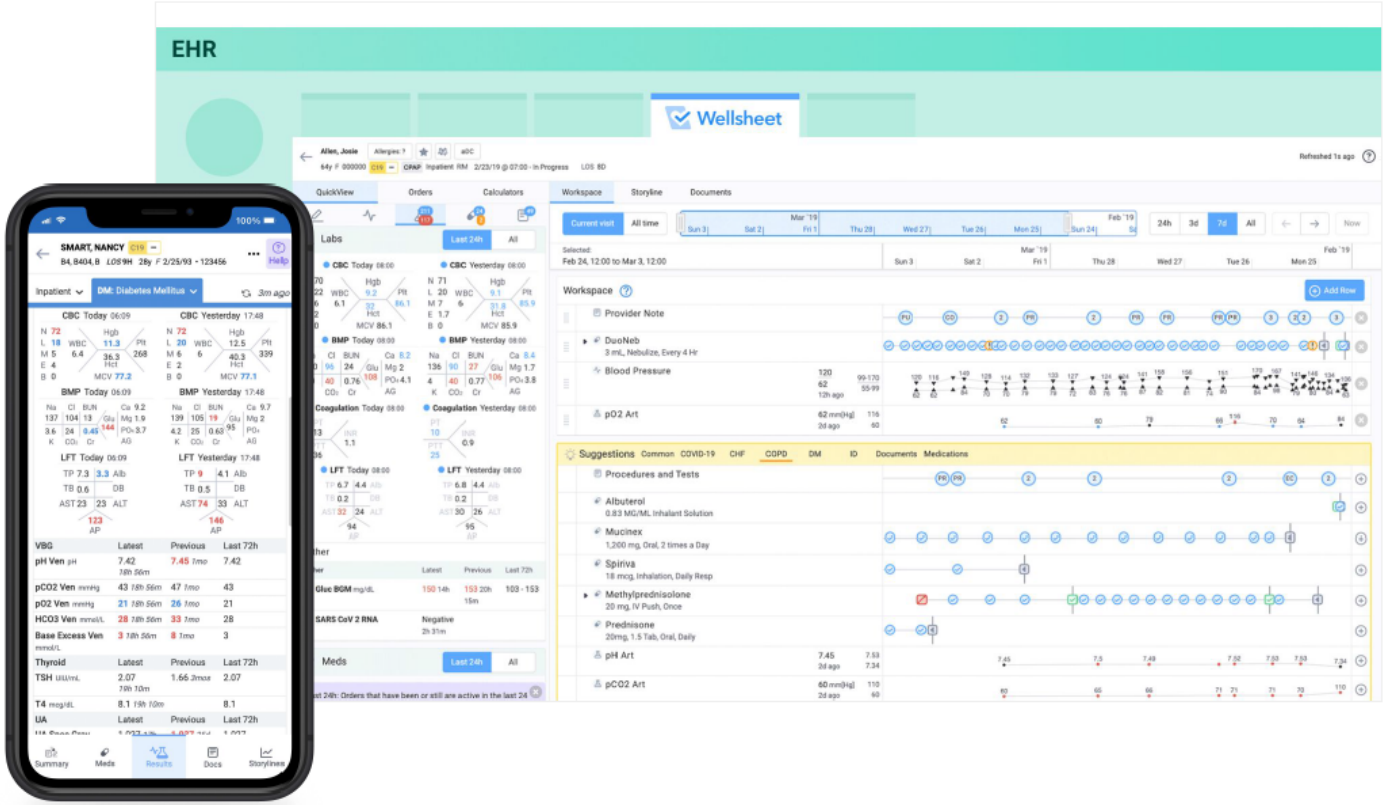


Predictive Workflows Improve Clinical Efficiency and EHR Experience

Wellsheet ***enhances provider productivity and user experience*** *by enabling predictive* ***chart-review****, care team* ***collaboration,*** *and* ***decision support***

Accessible directly within EHR*, as well as on* ***Wellsheet's mobile applications*** *(single sign-in via FHIR)*

FHIR®



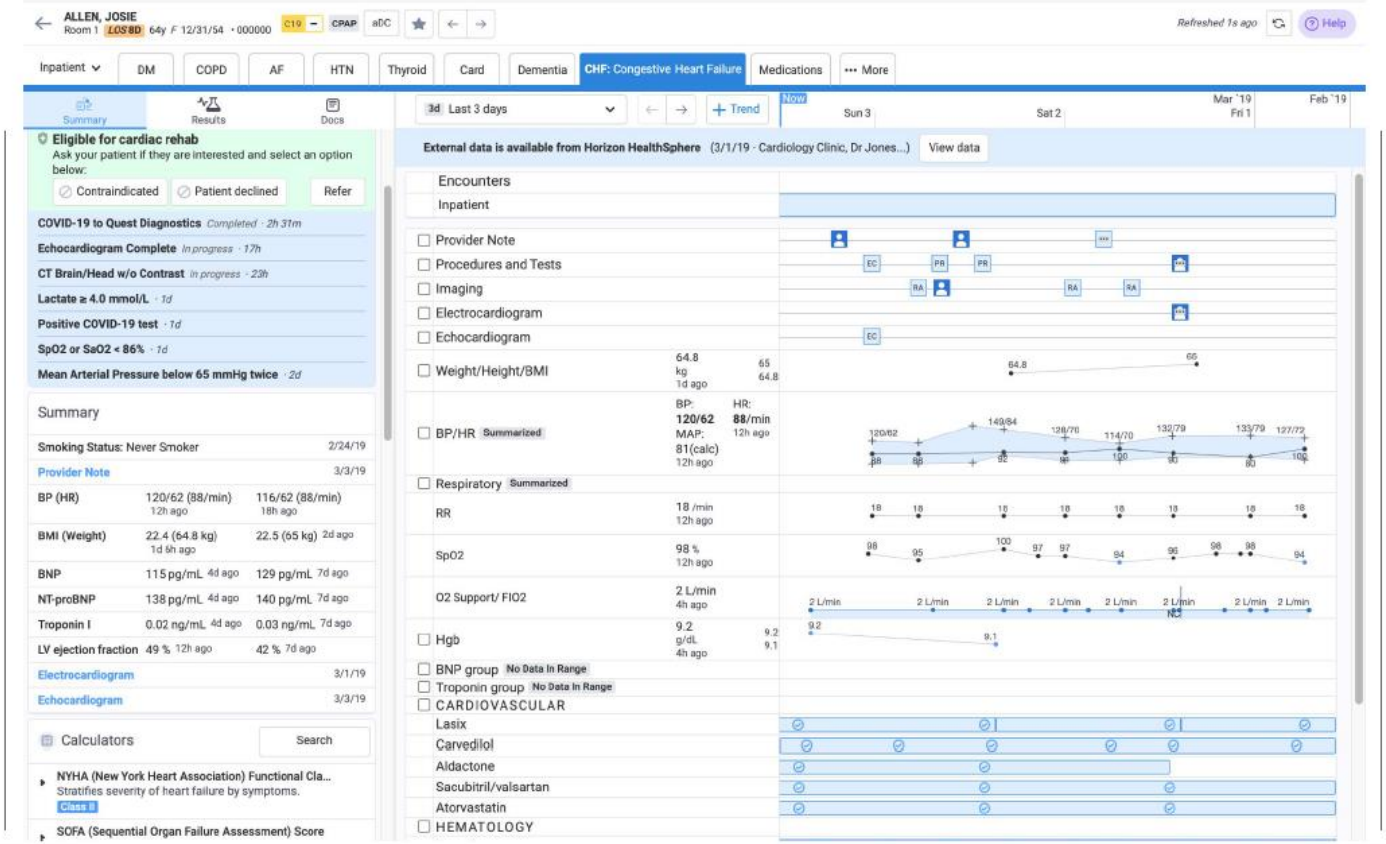
Patented Algorithms Predict and Prioritize Clinical Content Needed

Curated Decision Support

Pre-filled with data from EHR and can copy to notes

Drives referral patterns/trial recruitment

Configurable to client priorities



Predictive Data Display

Easily customizable by physicians

Driven by patented predictive models

Refined with user interaction

Wellsheet

Impact of Enabling a Predictive Workflow

- >40% Reduction in Time in EHR
- Reduces Length of Stay and Increases Patient Throughput
- Training in Minutes
- Fully API-integrated Deployment in Weeks
- 100% Customer Satisfaction (KLAS Research)
- Opportunity to incorporate external data and decision support resources

---

Contact us:

frachman@alliancechicago.org

craig.limoli@wellsheet.com

MAYO CLINIC

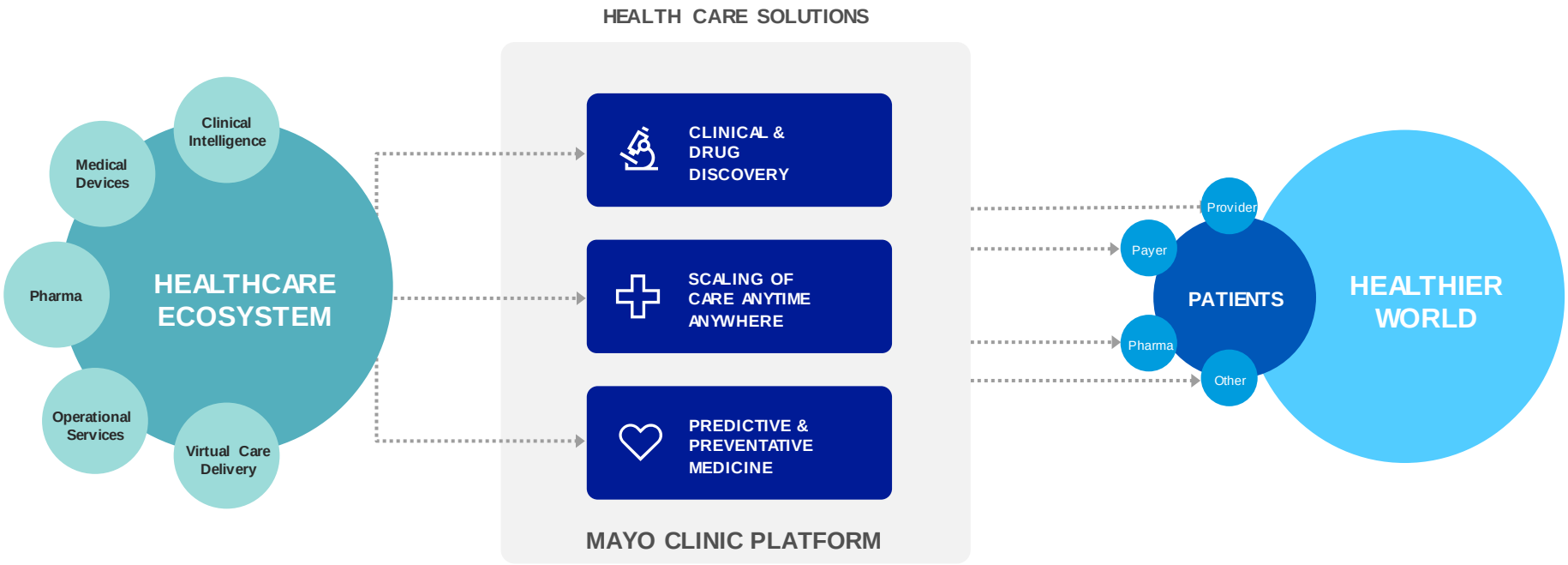
Mayo Clinic Platform

WE ENABLE NEW KNOWLEDGE, NEW SOLUTIONS AND NEW TECHNOLOGIES

Dr. John Halamka, President
Maneesh Goyal, Chief Operating Officer
Emily Wampfler, Sr. Director Product Management

www.mayoclinicplatform.org

ROLE IN THE HEALTHCARE ECOSYSTEM



OUR SUITE OF CORE PRODUCTS

GATHER

Collect, harmonize, de-identify and store

- Aggregate data from disparate sources to create one common repository of data
- Normalization of data to ensure standardization and cohesiveness across datasets
- De-identify data, making sure to adhere to patient security and privacy

DISCOVER

Develop algorithms and insights

- Explore de-identified data to build new or better algorithms
- Create analytics tools that provide insights
- Export results and insights

VALIDATE

Validation of models

- Evaluate model performance
- Utilize de-identified data to measure current model sensitivity and specificity
- Detect bias in the underlying data to minimize model bias

DELIVER

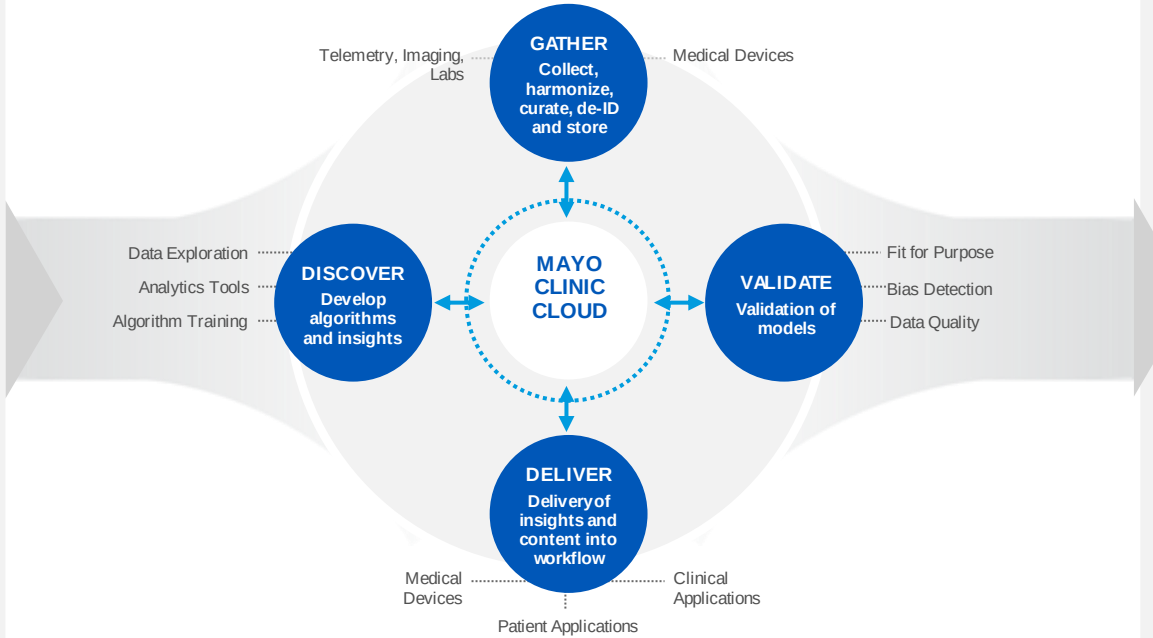
Delivery of insights and content into workflow

- Implement algorithms within a workflow in an IP protected manner
- Optimize data, insights and care recommendation visualization capabilities for patients and clinicians
- Provide access to curated libraries of provider and patient education
- Provide access to library of algorithms

MAYO CLINIC PLATFORM

VENDOR / MANUFACTURER ECOSYSTEM

- Clinical Intelligence
- Medical Device
- Pharma / Biotech
- Virtual Care
- Operational Improvement



CARE ECOSYSTEM

- Provider
- Payer
- Pharma
- Other

Thank You

www.mayoclinicplatform.org

Healthcare Demands Automation

Rohan D'Souza
Chief Product Officer, Olive
ONC AI Showcase
January 14, 2022

Humans have been innovating since 300 B.C. But now, we've entered a new frontier:

The Era of Intelligent Automation

"By 2030, Artificial Intelligence has the potential to add 16% — or **about $13 trillion** — to the global economy"

- *McKinsey Global Institute*

- **Analyzes Massive Amounts of Unstructured Data**: Identifies Patterns and Automation Opportunity
- **Mimics Human Logic:** Increased Used Case Complexity
- **Learns and Recommends:** Proactive Automation Ideation & Implementation

Healthcare **Demands** Intelligent Automation

Costs Continue to Skyrocket

$1T+ spent annually on administrative overhead

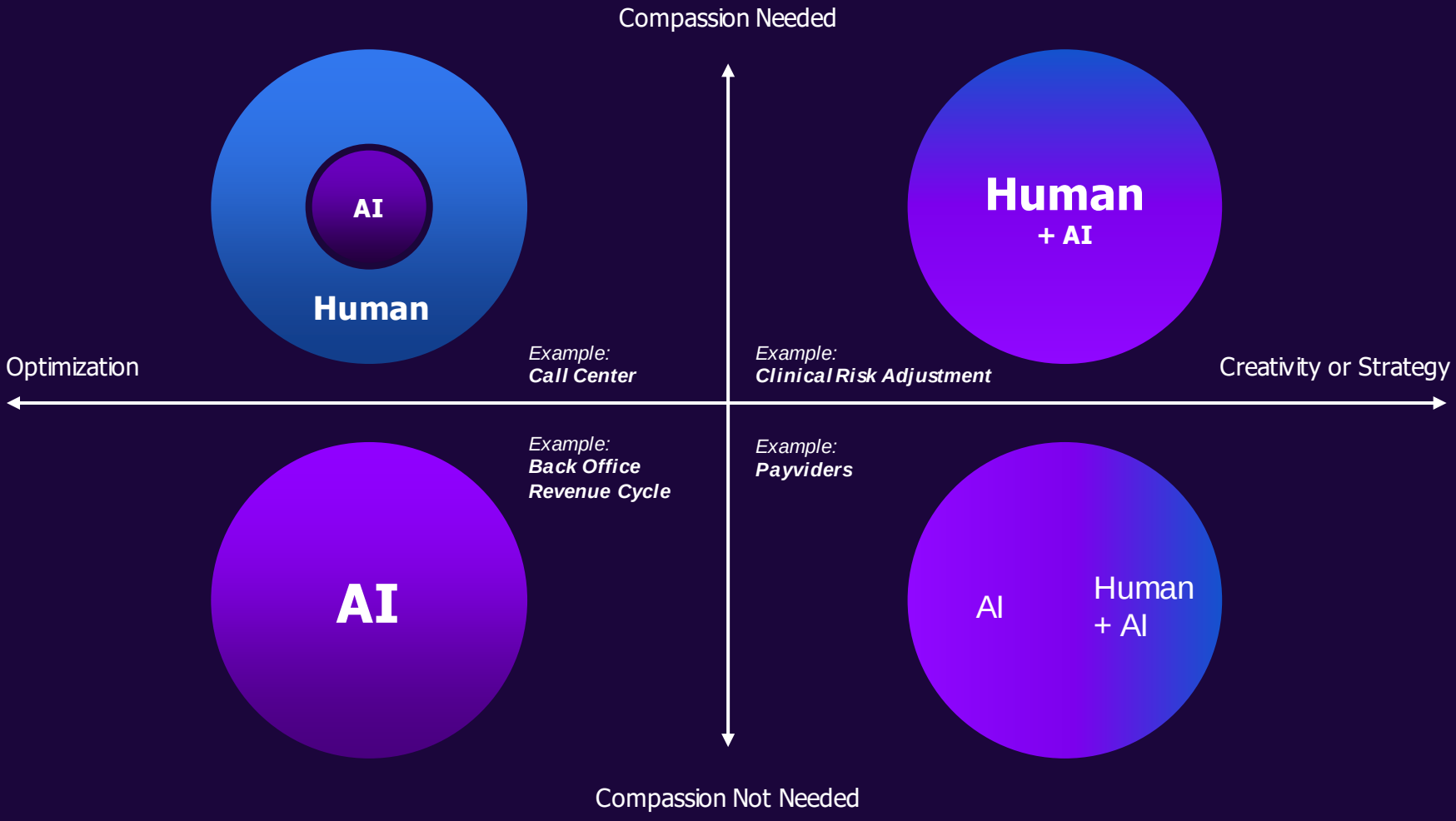
Degrading Patient Experience

91% of clinicians say that improving administrative processes is the most urgent need to improve quality of care[1]

Worsening Worker Burnout

92% of clinicians cite administrative tasks as major contributor burnout[1]

[1]Source: A study conducted by Olive and published in the Internet of Healthcare Report in August 2021


Compassion Needed
AI
Human
Human
+ AI
Optimization
Example:
Call Center
Example:
Clinical Risk Adjustment
Creativity or Strategy
Example:
Back Office
Revenue Cycle
Example:
Payviders
AI
AI
Human
+ AI
Compassion Not Needed

Envision Automation **Across the Entire Process**

Example Success with Prior Authorization Automation

Productivity
✓ **20-25% increase in staff** productivity

Write-offs
✓ **30-35%** average ***reduction*** in auth-related write-offs

Revenue
✓ **13-25% increase** in monthly revenue across service lines

Soon, healthcare will leapfrog other industries in innovation.

Nearly **8 in 10** healthcare executives believe **the industry will emerge as a leader**[1]

98% healthcare executives: **AI-led advancements will be widespread throughout U.S. healthcare by 2026**[1]

…And that **AI-led advancements will include fully automated data entry** (58%), **patient access to medical records from anywhere** (56%) and **virtual visits/remote monitoring will become the norm** (52%)[1]

[1]Source: A study conducted by Olive and published in the Internet of Healthcare Report in August 2021

Thank you

Bias in, Bias out: Datasets and AI

Kasia Chmielinski
The Data Nutrition Project
January 2022

DATA NUTRITION PROJECT

Kasia Chmielinski

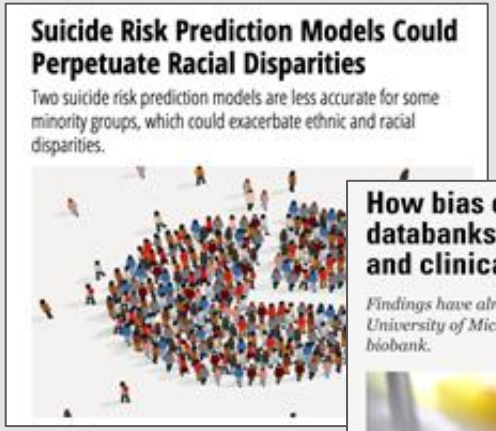
PRONOUNS: THEY / THEM

Co-Founder, Data Nutrition Project
Affiliate, Berkman Klein Center at Harvard
Sr. Researcher, Partnership on AI

Previously:
McKinsey & Company, U.S. Digital Service,
MIT Media Lab, ZestAI, Google

The Problem: **You Are What You Eat**

AI systems built on **incomplete or biased data** will exhibit problematic outcomes.



DATA NUTRITION PROJECT

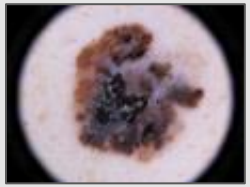
What happens if you **don’t eat well**?

Example: **Training data gaps become gaps in AI outcomes**

Veronica Rotemberg MD, PhD
Memorial Sloan Kettering

Ongoing work - not yet published

Common Use Case



Melanoma

Dermatologists:
71.9% Sensitivity

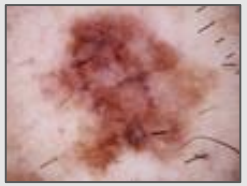
Top AI:
79.3% Sensitivity

Benign Nevus

Dermatologists:
92.8% Specificity

Top AI:
96.2% Specificity

Image Quality Variation



Melanoma
Clinic A

Top AI Algorithms:
90% of the time

Melanoma
Clinic B

Top AI Algorithms:
1.4% of the time

DATA NUTRITION PROJECT

What if you don’t even know **what you’re eating**?

… A **lack of transparency and data collection standards** precludes identifying bias, much less mitigating harms

JAMA Dermatology | Review

Lack of Transparency and Potential Bias in Artificial Intelligence Data Sets and Algorithms
A Scoping Review

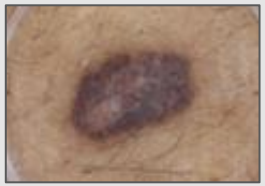
Roxana Daneshjou, MD, PhD; Mary P. Smith, MD; Mary D. Sun, MSCR; Veronica Rotemberg, MD, PhD; James Zou, PhD

"

RESULTS A total of 70 unique studies were included. Among these studies, 1 065 291 images were used to develop or test AI algorithms, of which only 257 372 (24.2%) were publicly available. **Only 14 studies (20.0%) included descriptions of patient ethnicity or race in at least 1 data set used. Only 7 studies (10.0%) included any information about skin tone in at least 1 data set used.**

Representation Gap:
Underrepresented populations, unusual anatomic sites

Melanoma
Darker Skin Tone



Melanoma
Darker Skin Tone

"

… if we don't collect this data, we cannot test for bias at all

DATA NUTRITION PROJECT

Data Documentation for Transparency: **Dataset Nutrition Labels**

The Data Nutrition Project: **Our Mission**

We empower data scientists and policymakers with practical tools to **improve AI** outcomes through **products** and **partnerships**, and in an **inclusive and equitable way**

Jess Yurkofsky
Design

Chris Kranzinger
Data Science

Kasia Chmielinski
Project Lead

Sarah Newman
Research Lead

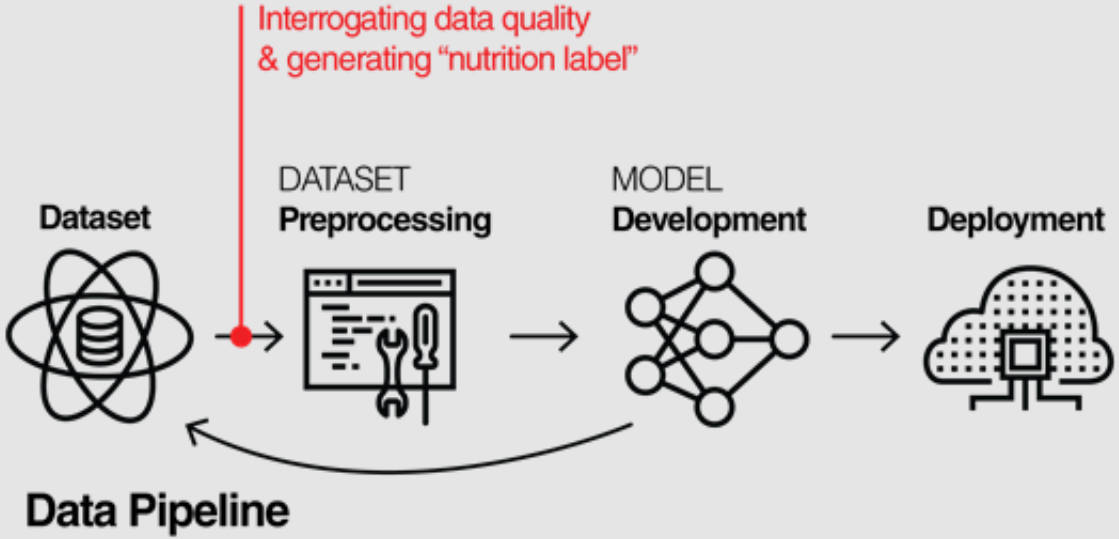
Kemi Thomas
Developer

Serena Oduro
Policy

Matt Taylor
Tech Lead

The Opportunity: **AI Development Modifications**

There is an opportunity to **interrogate data quality** and **drive data transparency** before building the model



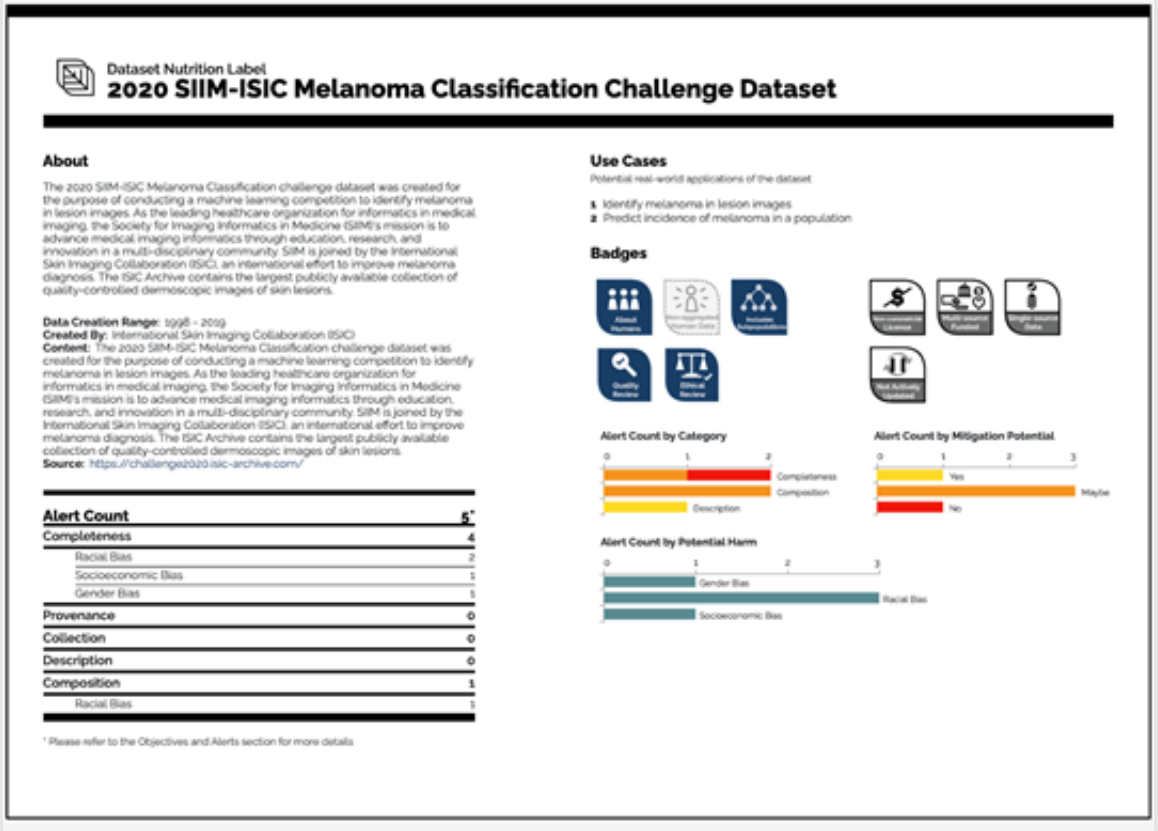
Empowering Practitioners: **Driving Meaningful Choice**

Standards help people understand the context and drive positive data creation behavior

Transparency helps people understand the impact and make informed decisions about whether and how to use the data

Nutritional Label for Datasets (2020)

https://datanutrition.org/labels/



Dataset Nutrition Label

2020 SIIM-ISIC Melanoma Classification Challenge Dataset

About

The 2020 SIIM-ISIC Melanoma Classification challenge dataset was created for the purpose of conducting a machine learning competition to identify melanoma in lesion images. As the leading healthcare organization for informatics in medical imaging, the Society for Imaging Informatics in Medicine (SIIM)'s mission is to advance medical imaging informatics through education, research, and innovation in a multi-disciplinary community. SIIM is joined by the International Skin Imaging Collaboration (ISIC), an international effort to improve melanoma diagnosis. The ISIC Archive contains the largest publicly available collection of quality-controlled dermoscopic images of skin lesions.

Data Creation Range: 1998 - 2019
Created By: International Skin Imaging Collaboration (ISIC)
Content: The 2020 SIIM-ISIC Melanoma Classification challenge dataset was created for the purpose of conducting a machine learning competition to identify melanoma in lesion images. As the leading healthcare organization for informatics in medical imaging, the Society for Imaging Informatics in Medicine (SIIM)'s mission is to advance medical imaging informatics through education, research, and innovation in a multi-disciplinary community. SIIM is joined by the International Skin Imaging Collaboration (ISIC), an international effort to improve melanoma diagnosis. The ISIC Archive contains the largest publicly available collection of quality-controlled dermoscopic images of skin lesions.
Source: https://challenge2020.isic-archive.com/

Alert Count	5*
Completeness	4
Racial Bias	2
Socioeconomic Bias	1
Gender Bias	1
Provenance	0
Collection	0
Description	0
Composition	1
Racial Bias	1

* Please refer to the Objectives and Alerts section for more details

Use Cases

Potential real-world applications of the dataset

1. Identify melanoma in lesion images
2. Predict incidence of melanoma in a population

Badges

Alert Count by Category

Alert Count by Mitigation Potential

Alert Count by Potential Harm

We focus on understanding and using the dataset

Potential harms or biases ....

- **Feature Selection**: Proxy characteristics, Data Definitions
- **Representation**: Sampling strategy, Curation and Collection
- **Manipulation & Imputed Values**: Preprocessing, Cleaning, Labeling, Access to Raw Data,
- **Completeness**: Missing information
- **Privacy**: Procedures and Protocols
- **Known Errors**: Are there any other errors, sources of noise, or redundancies in the dataset?

... mapped to use cases

- **Intended** uses
- Current or **known** uses
- **Limited** or cautioned uses
- **Not suitable for**

The Vision

Improving data quality through standards will:

1. Drive **robust data analysis practices** by making it easier and faster for data scientists to interrogate and select datasets.
2. Increase **overall quality of models** by driving the use of better and more appropriate datasets for those models
3. Enable the **creation and publishing of responsible datasets** by those who collect, clean and publish data

DATA NUTRITION PROJECT

Thank You!

Kasia Chmielinski
kc@datanutrition.org

Coding, Coverage, and Payment for AI Medical Services

An ONC Artificial Intelligence Showcase
Seizing the Opportunities
and Managing the Risks of
Use of AI in Health IT

Friday, Jan 14, 2022

Robert Jarrin, JD
Managing Member, The Omega Concern, LLC

Richard Frank, MD, PhD
CMO, Siemens Healthineers
Member, CPT EP

Co-chairs, AI Working Group, AMA Digital Medicine Payment Advisory Group

Coverage

- How to account for AI challenges to traditional healthcare business models
- AI is not reflected under existing practice expense (PE) methodologies (e.g., CMS)
- CMS has acknowledged its limitations to cover AI and issued an RFI in PFS proposed rulemaking for 2022
- RAND is helping CMS review data and methodology to establish PE valuation

Payment

- Medicare payment rate includes direct and indirect PE
- Physician Practice Information Survey (PPIS) as a source for expenses is outdated (last administered in 2007/2008)
- Emerging technologies do not rely on the typical equipment and hardware purchases but rely instead on software, licensing, and analysis fees (e.g., “pay per click”)
- Coverage and payment is inconsistent and based on “cross-walking” to payments for imperfectly analogous services

CPT Coding

- CPT (Current Procedural Terminologies) are descriptive terms and identifying codes for reporting medical services
- Coding also captures equipment, supplies, clinical services, used for billing
- Coding will need to reflect AI “work performed by machines”
- AMA created Appendix S to the CPT Code Set as a taxonomy to provide guidance for classifying AI

AMA DMPAG Charge to the AIWG
Regarding AI Products & Services

- Identify existing CPT conventions
- Identify coding gaps (via heuristics)
- Identify new framework(s) and criteria
- Advocate coverage and payment

MENU AMA Join Renew Enter Search Term

CPT early releases

CATEGORY I VACCINE CODES | CATEGORY III CODES | PLA CODES | **APPENDIX S: AI TAXONOMY** | AUDIO ONLY MODIFIER 93

CONTENTS

At its September 2021 meeting, the CPT® Editorial Panel accepted the addition of a new Appendix S to provide guidance for classifying various artificial intelligence/augmented intelligence (AI) applications. This guidance should be consulted for code change applications (CCAs) which describe work associated with the use of AI-enabled medical services and/or procedures.

This taxonomy provides guidance for classifying various artificial intelligence/augmented intelligence (AI) applications (e.g., expert systems, machine learning, algorithm-based services) for medical services and procedures into one of three categories: assistive, augmentative or autonomous. **The use of this appendix for guidance on coding is effective Jan. 1, 2022.**

https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures

AMA
AMERICAN MEDICAL ASSOCIATION

CPT® Appendix S: Artificial Intelligence Taxonomy for Medical Services and Procedures

Most recent changes to the CPT® Appendix S

- Addition of new Appendix S accepted by the CPT Editorial Panel at the September 2021 meeting.

Assistive Detects clinically relevant data

Augmentative Analyzes and/or quantifies data in a clinically meaningful way

Autonomous Interprets data and independently generates clinically relevant conclusions

- **I** Offers diagnostic or patient management options
- **II** Initiates diagnosis/management with alert/override opportunity
- **III** Initiates management; requires physician/QHP action to contest

https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures

Descriptors in CPT Codes will Anchor the Continuum of Product Description from Labels to Coverage Policy

FDA Product Description	CPT Code Descriptors	CMS Coverage & Payment
• Indication for Use • Degree of Autonomy • Proximity to Action • Seriousness of Impact • In/Exclusion criteria	Discrete, differentiable, and unique to the AI procedure, eg "Retinal Imaging with *Automated* PoC Diagnostic Report"	Valuation of the "Work done by Machines" Circumstances of use Business models
What clinicians want to know	Procedure and context of use	Role in episode of care

Appendix S to CPT Code Set
AI Taxonomy Implementation

I. Utilize taxonomy in CCA acceptance process

II. Publish and socialize AI Taxonomy article

III. Develop educational publications, webinars

IV. May develop an AI tech section for CCAs

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Co-chairs, AI Working Group, AMA Digital Medicine Payment Advisory Group

BREAK

(will start again at 4:00pm EST)

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

Closing Plenary –
A Panel Discussion

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

Closing Plenary Panel

The Office of the National Coordinator for Health Information Technology

Moderator:

Kathryn Marchesini, J.D.
Chief Privacy Officer, HHS/ONC
@PrivacyJD & @ONC_HealhtIT

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

Panelists;

John Halamka, M.D., M.S., President, Mayo Clinic Platform
@jhalamka & @MayoClinic

Amy Hall, Health Staff Director, House Ways and Means Committee
@WaysMeansCmte

Fred Rachman, Chief Executive Officer, AllianceChicago
@alliancecchs

Rohan D'Souza, Chief Product Officer, Olive
*@rohanpdsouza & @oliveai_*

Thank you for joining us today!

Please Note:
Recording of today's sessions and associated slides will be posted on www.HealthIT.gov in the near future!

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**

The Office of the National Coordinator for Health Information Technology

www.HealthIT.gov

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Email: Stephen.Konya@hhs.gov

Twitter: **#HealthIT_AI** and tag **@ONC_HealthIT**