Connecting for Better Health Meeting

Health AI Workshop

October 24, 2024

Connecting for Better Health

Advancing data sharing to improve the health of all Californians

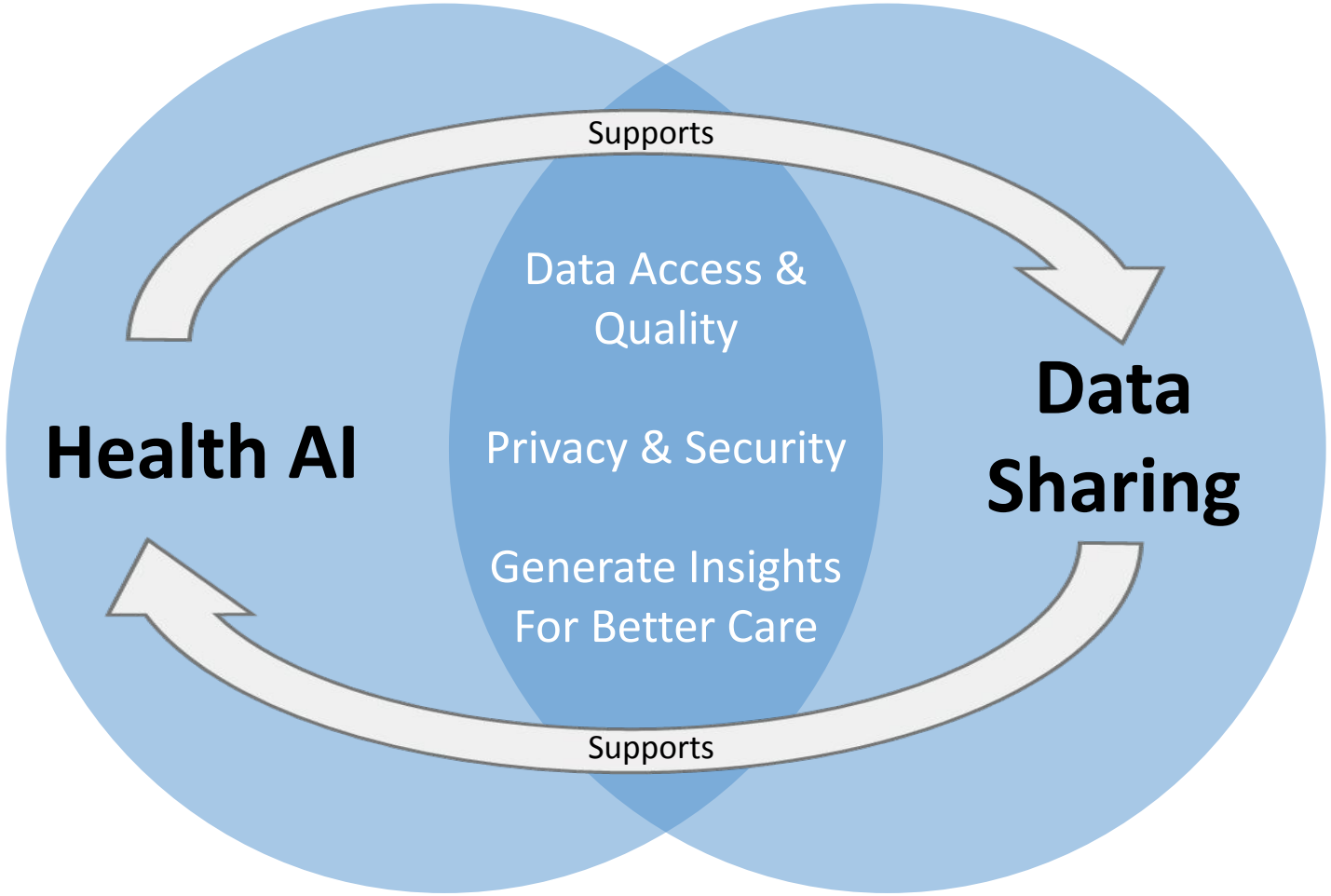
About The Coalition

Our Vision: Every Californian and their care teams have the information and insights they need to make care seamless, high quality and affordable

Policy Priorities

- **DSA Education & Implementation:** Promote awareness of the DSA and support data exchange implementation to realize the promise of AB 133
- **Funding:** Advocate for the state to dedicate continued funding for health and social services data sharing and encourage state agencies to seek federal match when and where appropriate
- **Integration of social services data:** Develop and communicate case studies and policy recommendations that support cross-sector data sharing, consent, and authorization
- **Advance DxF Governance, Enforcement, and Accountability:** Work towards the passage of DxF legislation, monitor state legislation and budgetary actions related to data sharing, and provide critical feedback to CDII and other state agencies to resolve challenges

Health AI & Data Sharing



Workshop Objectives

1. Understand federal and state activity underway to advance trusted health AI

2. Consider linkages among health and social data sharing and health AI

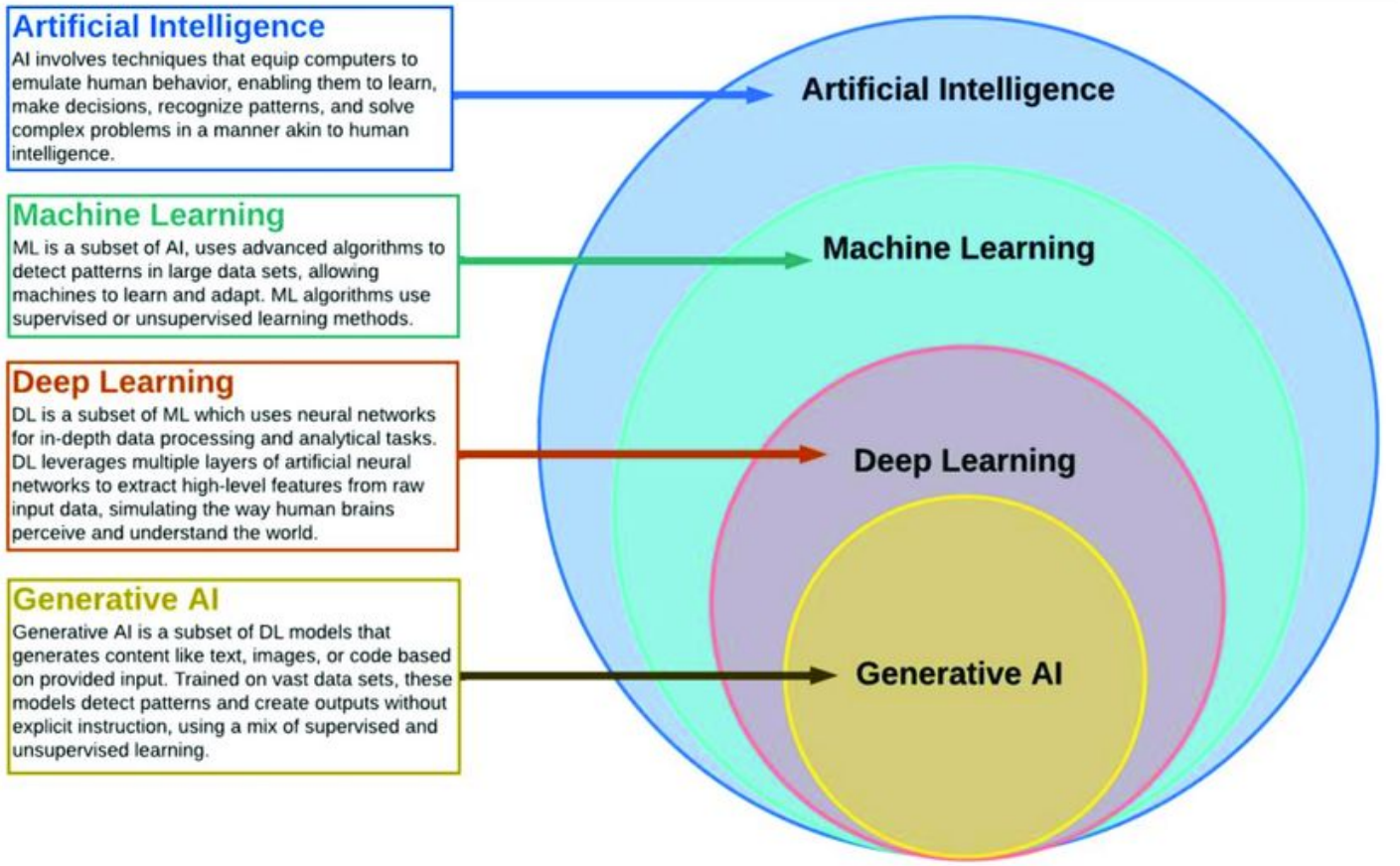
3. Inform C4BH's engagement in health AI policy and education

Workshop Agenda

No.	Item	Minutes
1	Welcome	5 minutes
2	Health AI: Introduction and Grounding	10 minutes
3	Industry Initiatives: VALID AI ● Kamal Jethwani, MD MPH	10 minutes
3	The Role of Health Data Utilities in Supporting Heath AI ● Jolie Ritzo, MPH, Civitas Networks for Health ● Dr. Ahmad Alkasir, DrPH, Ellison Institute of Technology	20 minutes
4	Discussion, Key Considerations	10 minutes
5	Wrap-Up and Announcements	5 minutes

Health AI: Introduction and Grounding

What is Health AI?



AI Use Cases in Health Care

- **Tools to Support Providers**
  Documentation, administrative workflows, chatbots to triage
- **Remote Patient Monitoring**
  Pattern recognition, predictive analysis, anomaly detection
- **Medical Diagnosis**
  Imaging, early detection, analyze symptoms
- **Treatment**
  Simulate treatments and outcomes, identify drug interactions
- **Research**
  Cancer, clinical trials
- **Data Management**
  Cleaning, extracting, integrating, organizing

Health AI: Threats of Bias and Harm

“Data is inherently biased by the healthcare system that we live in today”

- Dr. Micky Tripathi, HHS Chief AI Officer, [10/8/2024]

The Washington Post
https://www.washingtonpost.com › health › 2019/10/24

Racial bias in a medical algorithm favors white patients ...

Oct 24, 2019 — A widely **used algorithm** that flags **patients** for extra **medical care** is biased against **black patients**, a study found.

Harvard T.H. Chan School of Public Health
https://www.hsph.harvard.edu › ecpe › how-to-prevent-...

Algorithmic Bias in Health Care Exacerbates Social Inequities

Mar 12, 2021 — However, **AI** can suffer from **bias**, which has striking implications for **health** care. The term “algorithmic **bias**” speaks to this problem. It ...

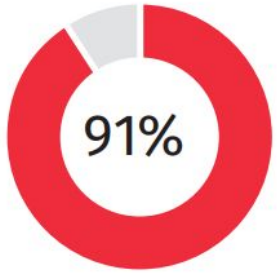
The Regulatory Review
https://www.theregreview.org › 2023 › July › 4

Patient Versus Algorithm

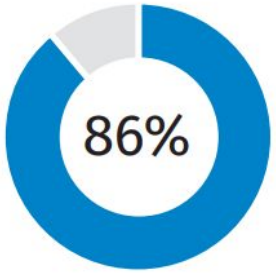
Jul 4, 2023 — As a result, the tool apparently encouraged providers to **double-book low-income** patients, who are more likely to miss **appointments** due to ...

Wolters Kluwer

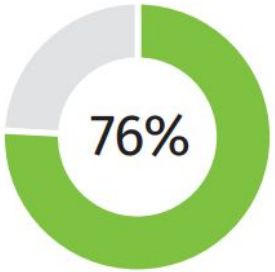
Despite their enthusiasm, physicians are wary of which GenAI tools they would be comfortable using. What would make doctors more comfortable?



source content created by doctors and medical experts

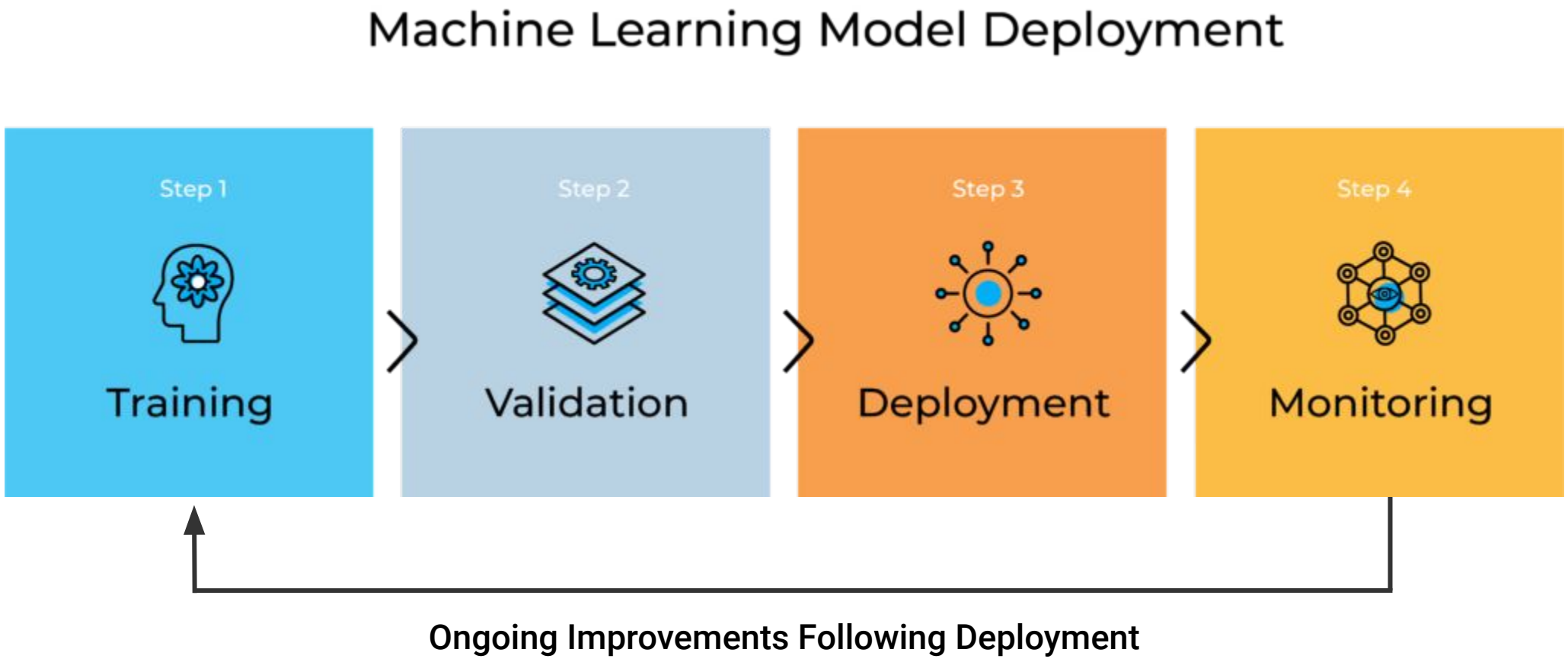


vendor transparent about where information came from, who created it, and how it was sourced



technology from established company

Opportunities for AI Assurances



Federal Actions Impacting Health AI

1. **July 2022** - White House announces AI developer commitments for safe, secure, and transparent AI
2. **October 2022** - White House releases AI Bill of Rights Blueprint to outline AI principles
3. **January 2023** - NIST releases AI Risk Management Framework
4. **October 2023** - White House releases Executive Order on the Safe, Secure, and Trustworthy Development and Use of AI with directives for federal agencies (now completed)
5. **March 2024** - HTI-1 Final Rule establishes algorithm transparency requirements for EHRs that are certified health IT by January 1, 2025
6. **January 2025** - Anticipate HHS AI Strategic Plan for life sciences and healthcare

Key Executive Order Directives for the U.S. Department of Health and Human Services (HHS)

- Establishment of departmental Chief AI Officers, with Dr. Micky Tripathi appointed at HHS to lead the HHS AI Strategy
- Maintain HHS AI use case inventory and share custom-developed AI code as open-source
- Create a safety program to receive reports of and address harmful health AI practices
- Develop a framework for assessing and monitoring AI performance and quality with an HHS AI Task Force

(Access the Compliance Plan)

California State Actions on AI

1. **September 2023 - Executive Order N-12-23 to prepare state entities for AI. Directive include:**
   - Studying the development, use, and risk of GenAI
   - Guidelines for public sector procurement, use, and training of GenAI
   - A report on GenAI risks and benefits for state entities
   - Guidelines for state entities to self-assess impact of GenAI adoption
   - Evaluated potential impact of GenAI on regulatory issues on ongoing basis

2. **March 2024 - CalHHS IT and Data Strategic Plan references having a forward-looking perspective on GenAI to support access and delivery of high-quality services**
   - Identify opportunities while guarding against risks to leverage new possibilities
   - Notes that GenAI requires measures to address insufficiently guarded systems and harms
   - Ensure responsible GenAI with proper guardrails and engagements in place from Governor's Executive Order

3. **September 2024 - New state initiatives to advance safe and responsible AI, including:**
   - Engagement of top AI experts to develop "workable guardrails" for deploying GenAI, focusing on analysis of the capabilities and risks of frontier models
   - Exploring GenAI use in the workplace with academia, labor organizations, and the private sector
   - Collaborating with AI developers to identify innovative solutions for housing and homelessness

4. **September 2024 - Governor Newsom signed 17 bills covering GenAI deployment and regulation**

2024 Health AI California State Legislation

No./Author	Summary	Impact
AB 2013 (Irwin) ENACTED	Requires AI developers to publicly post high-level summaries of datasets used to train GenAI developed or modified after January 1, 2022 with certain exceptions for AI used for national security and integrity.	Increases AI transparency with public disclosures of training data.
AB 3030 (Calderon) ENACTED	Requires health care providers using AI for clinical communications to include AI disclaimers with clear instructions to connect with a human, exempting communications reviewed by a licensed or certified provider. Violations are subject of state medical boards, as appropriate.	Increases AI transparency from health care providers for clinical communications.
SB 896 (Dodd) ENACTED	Requires GenAI benefits and risk report from Executive Order N-12-23 to be updated as needed and requires the Office of Emergency Services to risk assess potential GenAI threats to CA's critical infrastructure. State must disclose AI use in communicating government services and benefits.	Increases state monitoring of GenAI risks in particular for state infrastructure, and increased AI transparency in state communications.
SB 1120 (Becker) ENACTED	Establishes requirements for health plans and disability insurers using AI, algorithm, or software tools for utilization review or management decisions to be compliant with specified requirements, including that it is fairly and equitably applied, does not discriminate, is open for state audit, and medical necessity decisions are made by a licensed decision or health care professional.	Regulates how health plans and disability insurers can use AI to make utilization decisions and prohibits AI use for medical necessity determinations.
SB 892 (Padilla) VETOED	Requires the Department of Technology to establish an automated decision systems procurement standard, which would include risk and equity assessments, and require state contracts to comply with this standard.	No common risk & equity AI standard across state agencies and departments, but they must still develop guardrails to deploy AI ethically and responsibly to reduce risks (EO N-12-23).
SB 1047 (Weiner) VETOED	Requires AI developers to implement safety and security protocol, use third-party auditors to perform and submit annual compliance certifications, and prohibit AI use if unreasonable risk could cause harm. Establishes a governing board and division, whistleblower protections, and civil action for unlawful acts.	Large AI models deployed in California are not regulated by the state with safety, security, and risk protocols at this time.

Industry Initiatives: VALID AI

Dr. Kamal Jethwani, MD MPH

Managing Partner and CEO

Decimal.health

Industry Initiatives for Responsible Health AI

VALID AI - Consortium of 50+ health systems and partners to rapidly advance GenAI validation and governance

- Social Vital Signs and SDOH accelerator program

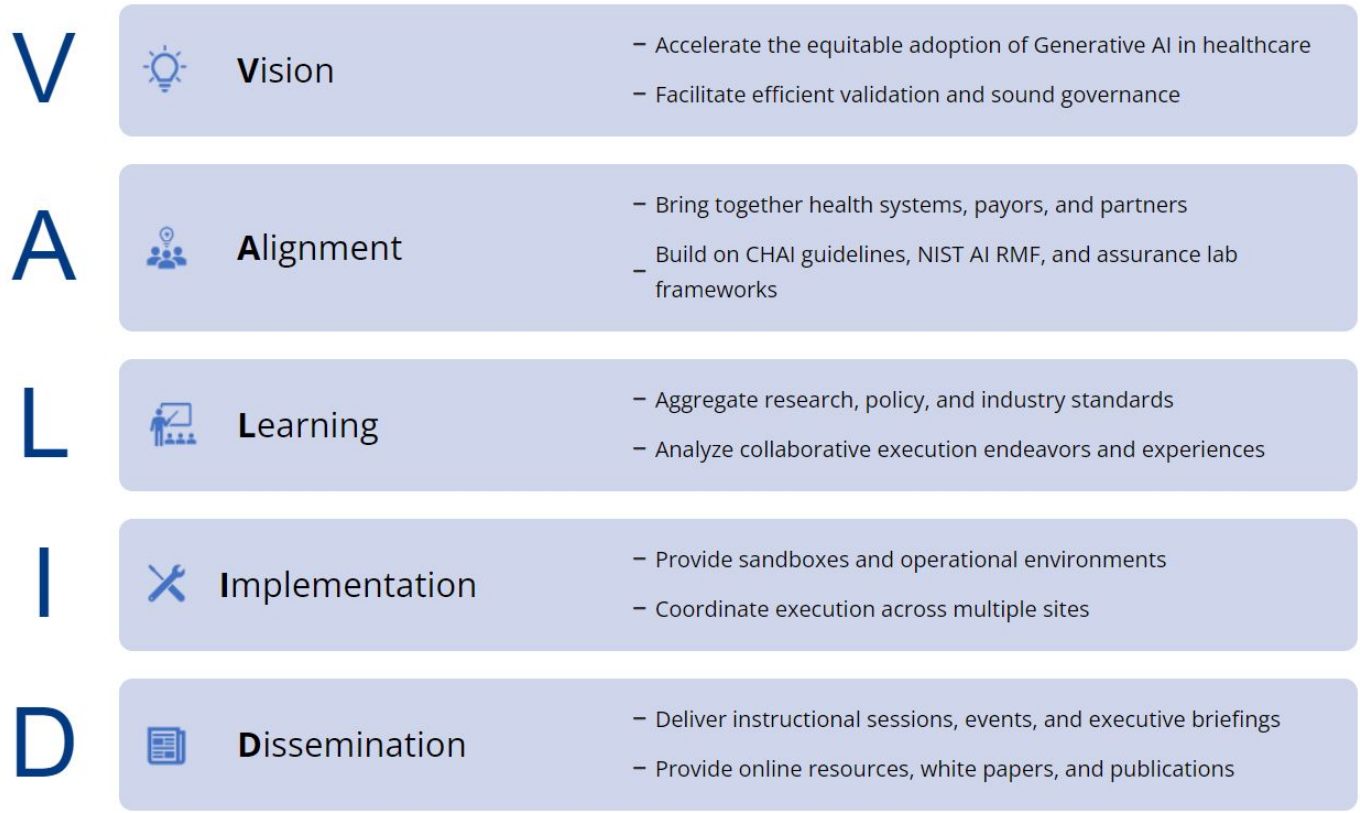
Coalition for Health AI (CHAI) - Collaborative developing guidelines for responsible health AI

- Deployment framework for Health AI
- Quality Assurance Labs

Health AI Partnership - Framework on Localized Quality Assurance

EPIC - Open-source tool to validate AI models

NYC Coalition to End Racism in Clinical Algorithms - Remove and address race-based algorithms



The Role of Health Data Utilities in Supporting Health AI

Jolie Ritzo, MPH

Vice President of Strategy and Network Engagement, Civitas Networks for Health

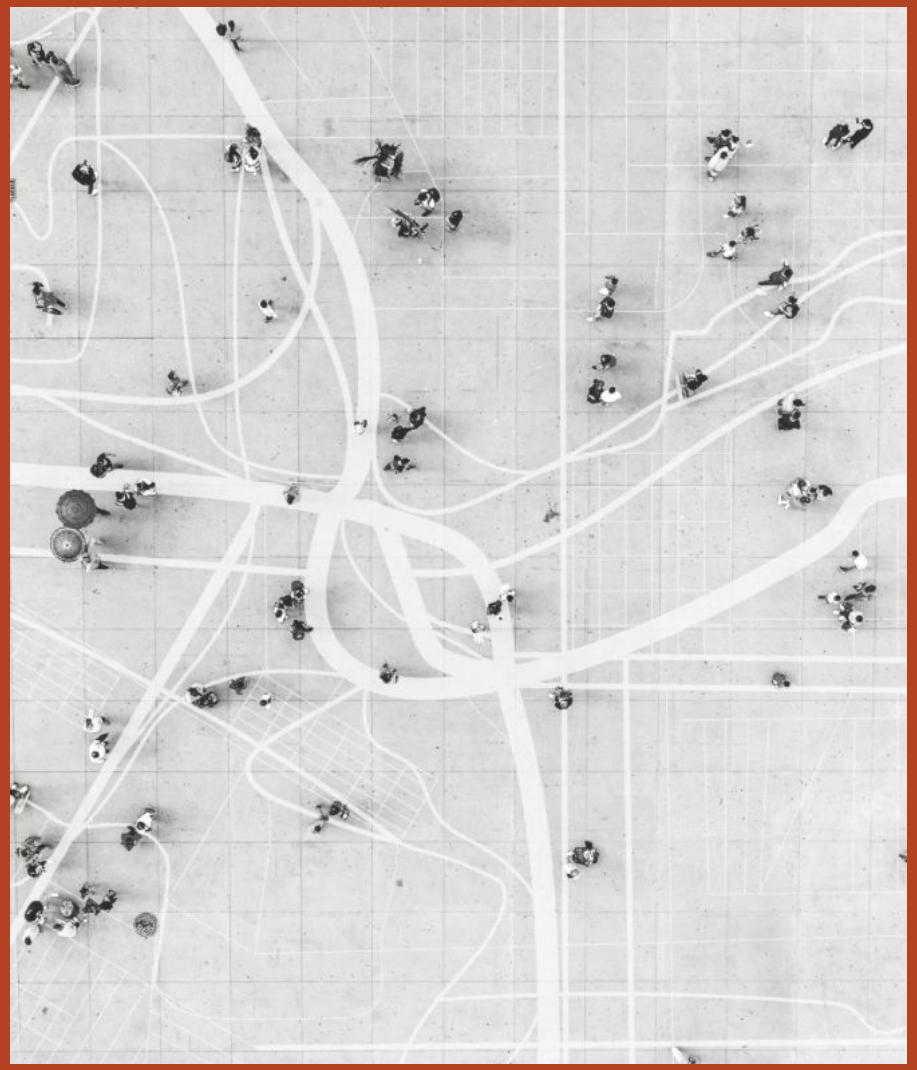
Dr. Ahmad Alkasir, DrPH, MPH

Program Manager, Ellison Institute of Technology

CIVITAS
Networks for Health

Civitas Networks for Health and Health Data Utilities

Jolie Ritzo
Civitas Networks for Health
October 24, 2024

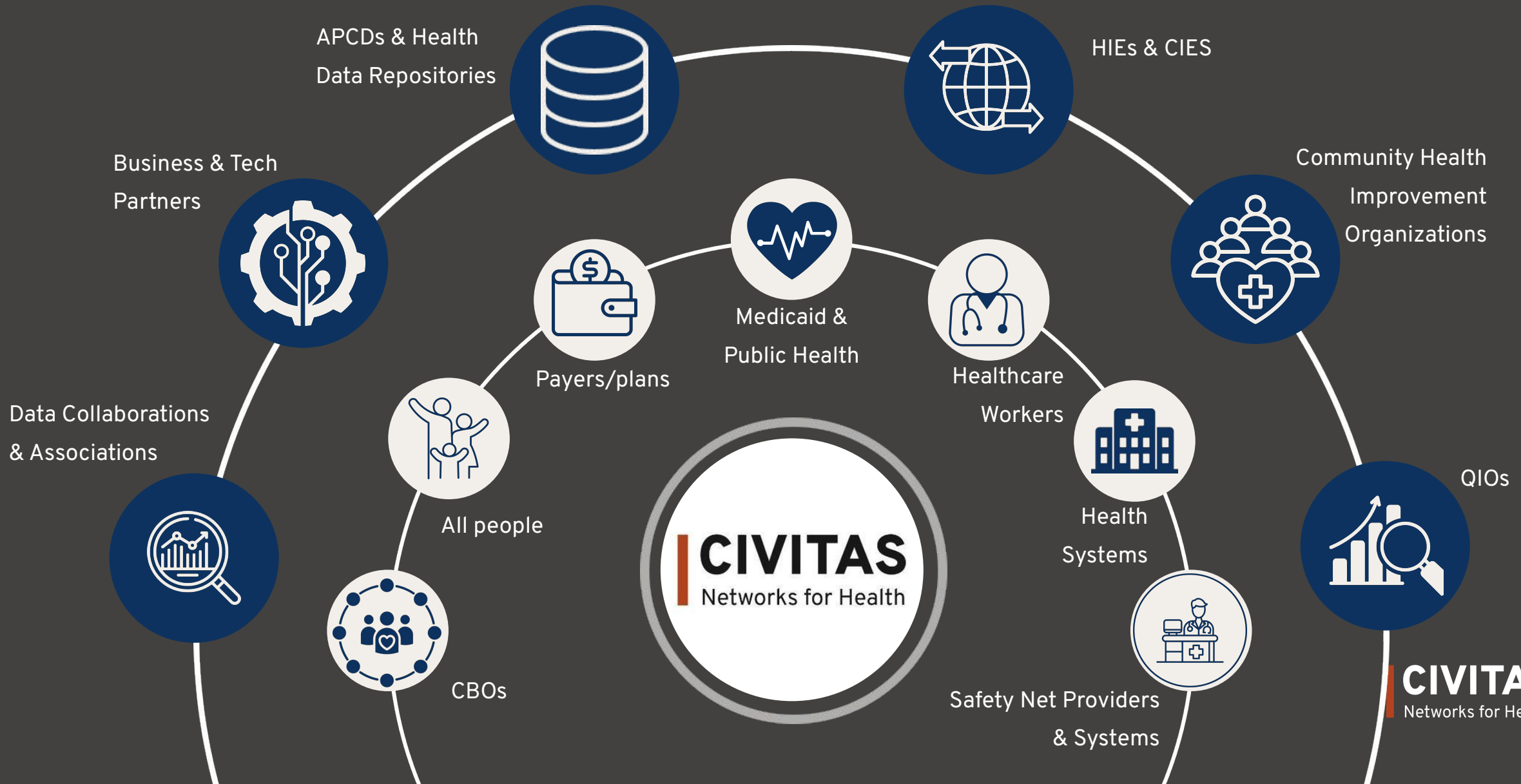


Regional innovation, national impact.

Our vision: Communities across the country are thriving and healthy, realizing the full potential of data-driven, multi-stakeholder, and cross-sector approaches to health information exchange and health improvement.

CIVITAS
Networks for Health

WHO CIVITAS SERVES



WHAT IS CIVITAS NETWORKS FOR HEALTH?

DATA

DOING

CIVITAS
Networks for Health

THE EMERGENCE OF HEALTH DATA UTILITIES

HDUs are regional or statewide entities that combine, enhance, and exchange electronic health data across care and service settings for treatment, care coordination, quality improvement, and public and community health purposes. They serve as health equity infrastructure and enable specific, defined use cases with extra safeguards to ensure patient privacy and protection.

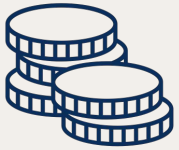
They build on existing technical, organizational, and trust infrastructure in states and regions.

CIVITAS
Networks for Health

EMERGING HDU CHARACTERISTICS

Neutrality and flexibility in meeting stakeholders' goals

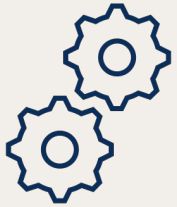
Designated Authority for specific services



Sustainable financing

Connected region or state geography

Multi-stakeholder, cross-sector participation



Modular infrastructure and advanced technical services

Public-private partnerships

Inclusive governance strategy

Leverage state and local program and data authority

CIVITAS
Networks for Health

Ellison Institute
of Technology

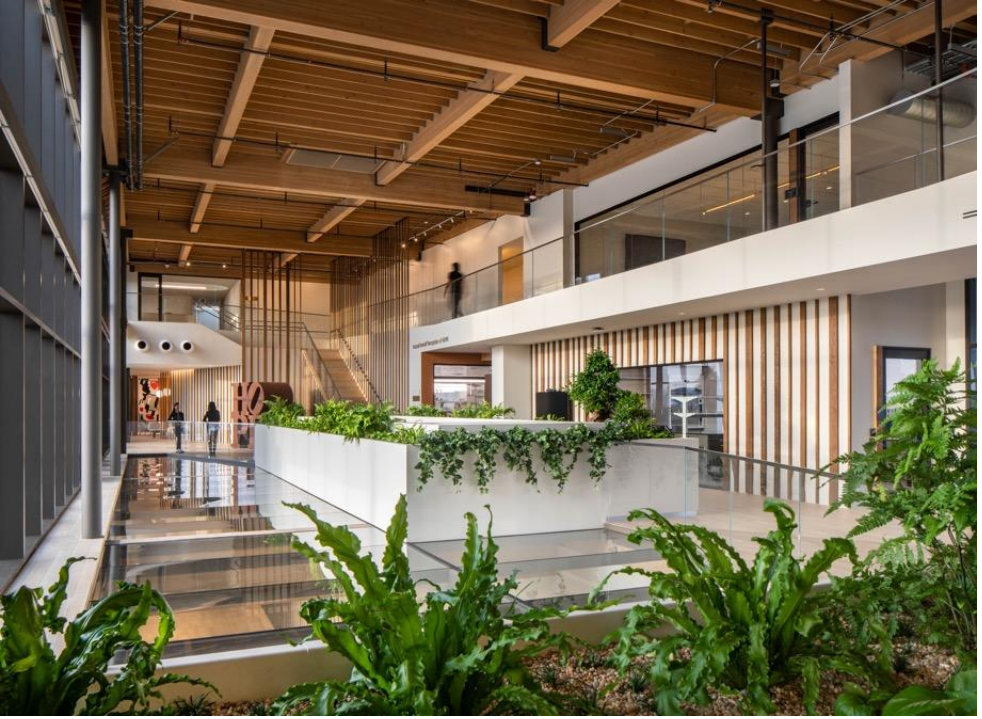
About EIT

Ahmad Alkasir DrPH| 10.24.2024

Ellison Institute of Technology

Science & Engineering for Humanity

The Ellison Institute of Technology's mission is to develop and deploy technology in pursuit of solving some of humanity's most challenging and enduring problems. Guided by world leaders, scientists and entrepreneurs, EIT seeks to accelerate innovation in health and medical science, food security and sustainable agriculture, climate change and clean energy, and government innovation and era of artificial intelligence.



ABOUT EIT LA

Established in 2009, EIT brings together a diverse set of clinicians, scientists, and thought leaders to collaborate and drive innovation. Our unique model brings a cancer and wellness clinic and research laboratories under one roof.

Medical Science & Healthcare

Our facility brings every aspect of cancer care under one roof.

On a daily basis, our aim is to integrate patient care, research, data analytics, and applied technology to optimize treatment for each patient. Our ultimate aim is to convert the exceptional experiences of a few outliers into typical outcomes for nearly everyone.

NEJM AI publication discussing data reuse implications for health AI and the role of HDUs (1 of 3)

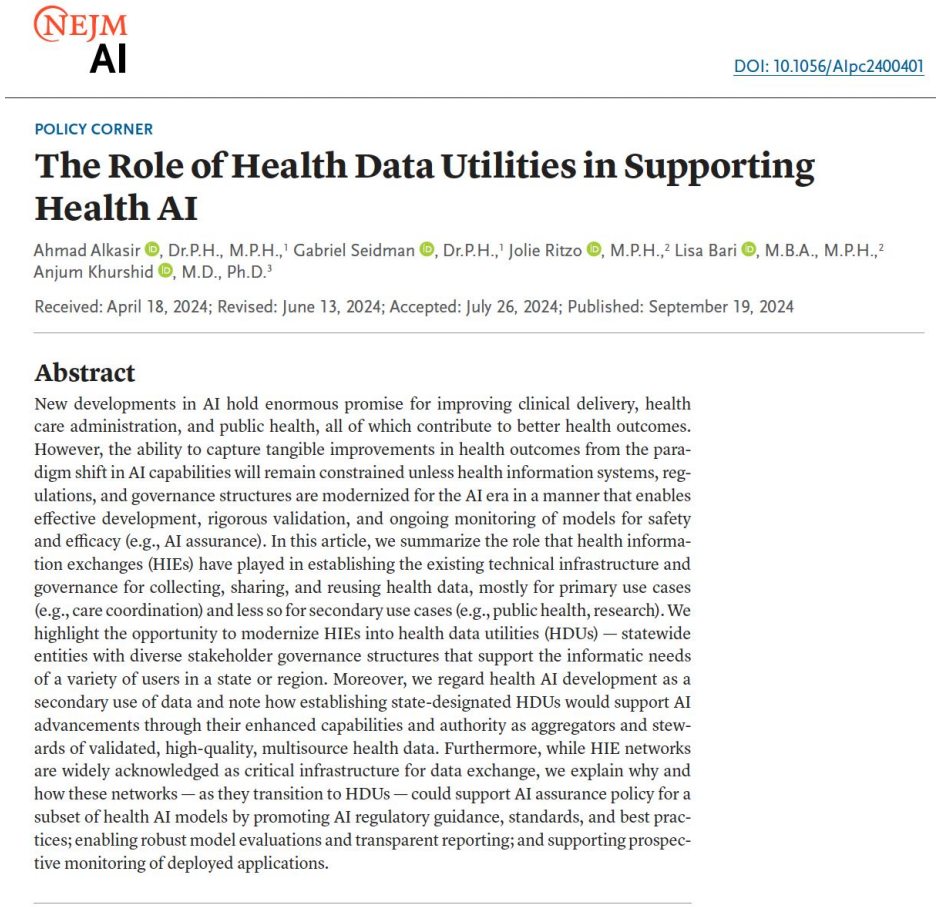
Key Arguments

Translating AI advances into health outcomes requires health information systems, regulations, and governance structures that enable:

i. Robust AI model developments relying on high-quality data
ii. Rigorous validation of models prior to deployment
iii. Ongoing monitoring of models for safety and efficacy (i.e., 'AI assurance' functions)

AI development is a form of secondary reuse of data. Hence, AI developments would benefit from modernizing capabilities and governance across data types (clinical, public health, social determinants of health, claims, administrative, and other relevant data) for the AI era.

HDUs could support these requirements, and are already receiving Congressional recognition, with Senate Report 118-84 defining HDUs and directing CDC, ONC, and other agencies to support state-designated HDUs.



NEJM AI

DOI: 10.1056/AIpc2400401

POLICY CORNER

The Role of Health Data Utilities in Supporting Health AI

Ahmad Alkasir, Dr.P.H., M.P.H.,[1] Gabriel Seidman, Dr.P.H.,[1] Jolie Ritzo, M.P.H.,[2] Lisa Bari, M.B.A., M.P.H.,[2] Anjum Khurshid, M.D., Ph.D.[3]

Received: April 18, 2024; Revised: June 13, 2024; Accepted: July 26, 2024; Published: September 19, 2024

Abstract

New developments in AI hold enormous promise for improving clinical delivery, health care administration, and public health, all of which contribute to better health outcomes. However, the ability to capture tangible improvements in health outcomes from the paradigm shift in AI capabilities will remain constrained unless health information systems, regulations, and governance structures are modernized for the AI era in a manner that enables effective development, rigorous validation, and ongoing monitoring of models for safety and efficacy (e.g., AI assurance). In this article, we summarize the role that health information exchanges (HIEs) have played in establishing the existing technical infrastructure and governance for collecting, sharing, and reusing health data, mostly for primary use cases (e.g., care coordination) and less so for secondary use cases (e.g., public health, research). We highlight the opportunity to modernize HIEs into health data utilities (HDUs) — statewide entities with diverse stakeholder governance structures that support the informatic needs of a variety of users in a state or region. Moreover, we regard health AI development as a secondary use of data and note how establishing state-designated HDUs would support AI advancements through their enhanced capabilities and authority as aggregators and stewards of validated, high-quality, multisource health data. Furthermore, while HIE networks are widely acknowledged as critical infrastructure for data exchange, we explain why and how these networks — as they transition to HDUs — could support AI assurance policy for a subset of health AI models by promoting AI regulatory guidance, standards, and best practices; enabling robust model evaluations and transparent reporting; and supporting prospective monitoring of deployed applications.

Implications for health AI - Continued (2 of 3)

Role of State Health Data Utilities

Serve as state-designated entities responsible for collating and standardizing data, enabling the aggregation of more comprehensive, multisource, representative health datasets:

i. HDUs would formalize standards and governance for the exchange and integration of fragmented health data.

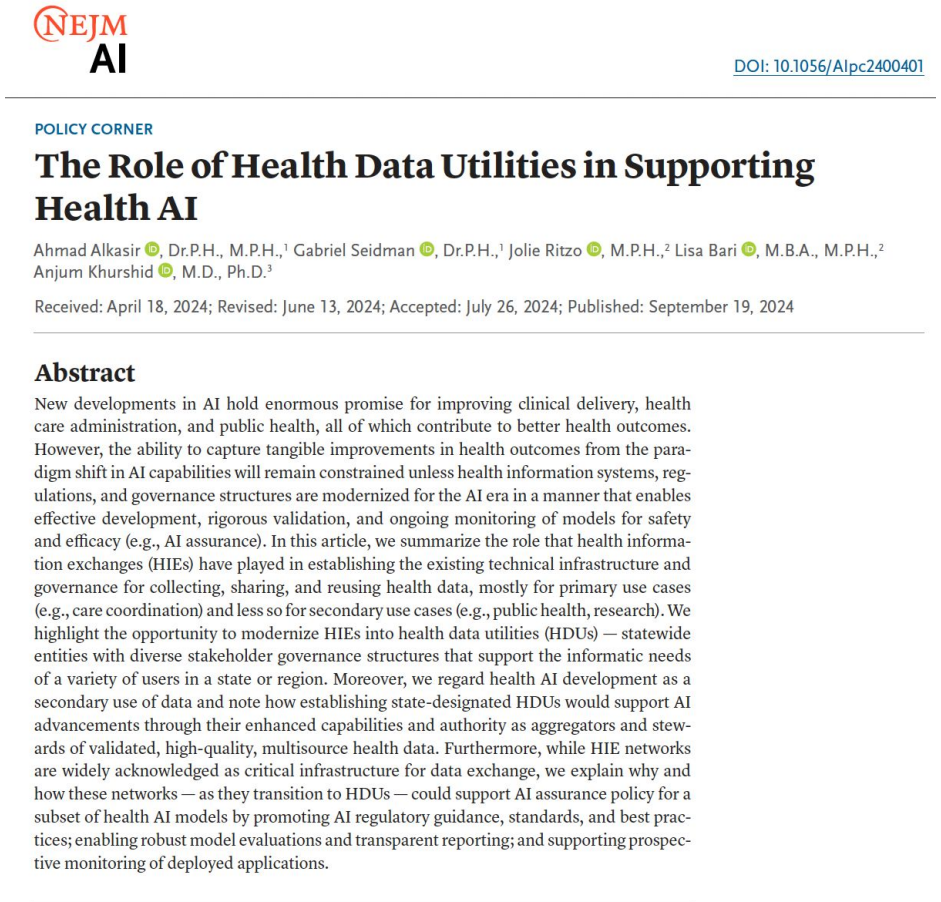
ii. HDUs would enable the integration of clinical and nonclinical data in standardized formats, clear provenance, preserved data quality, and implement privacy and security safeguards.

All these functions are critical for ensuring AI safety, effectiveness and equity.

Serve as public stewards of validated datasets for AI development:

i. HDUs could host and provide appropriate access to multisource data for AI training and testing, including deidentified or synthetic data for performance evaluations.

ii. Promote a fair and competitive AI ecosystem, as prescribed by White House executive orders, by providing small and medium-sized organization that have limited development capacity with resources and technical assistance.



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Implications for health AI - Continued (3 of 3)

Role of State Health Data Utilities

Finally, considering that:

i. Well-recognized risks in deploying health AI (e.g., patient harm, exacerbating inequities);

ii. Potential for prospective performance decay with subtle changes in data structures

iii. EHR-based model-to-model interactions revealed in simulation studies

iv. The relative ease of developing AI (compared to drugs) surpasses FDA's capacity for oversight. Also, many models fall outside FDA's regulation for AI (e.g., public health surveillance, health administration models)

HDUs may potentially support health AI governance, including by:

a) Promoting regulatory guidance and AI assurance policy, standards, and best practices.

b) Supporting evaluations and life cycle oversight for a subset of health AI, including through enabling localized testing and transparent reporting.

However, significant mandates and incentives are needed to establish these functions for HDUs.

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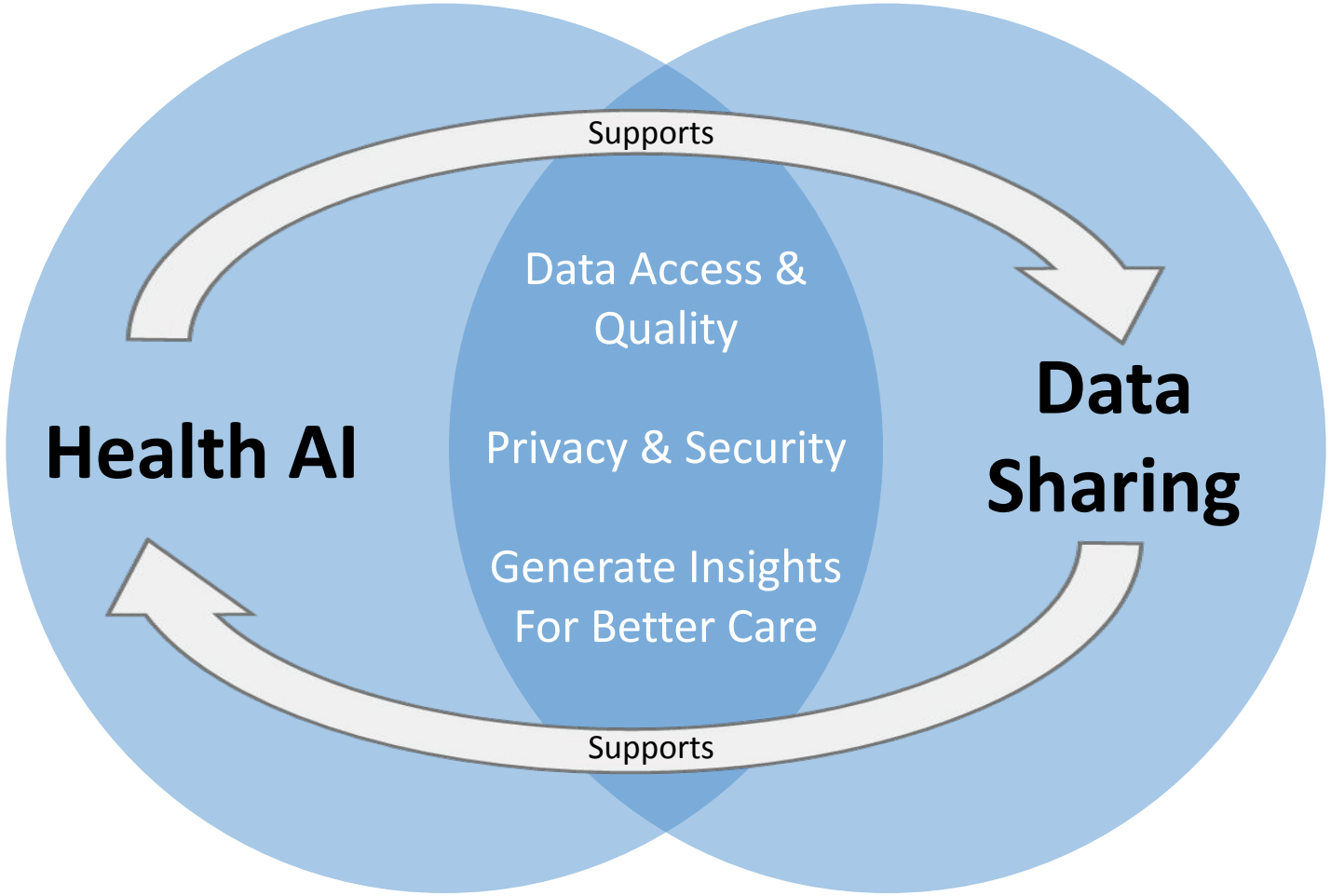
Discussion: C4BH Health AI Considerations

- *DxF*
- *Governance*
- *Guidance*
- *Fair and Competitive*
- *Regulation*
- *Transparency*



- *Validation*
- *Monitoring*
- *Safety*
- *Efficacy*
- *Best Practices*
- *Policy and Legislation*

Wrap-Up and Next Steps

Upcoming Webinars & Events

- **October 29, 1:30-3PM PT:** ITUP 2024 Election Policy Forum | Register here
- **October 28, 12-1PM PT:** CalHHS CDII DxF Standards Committee Meeting #3 | Register here
- **November 7, 12:30-3PM PT:** CalHHS CDII DxF Implementation Advisory Committee Meeting | Register here
- **November 8, 1-2PM PT:** CalHHS CDII DxF Technical Advisory Subcommittee Meeting #4A | Register here
- **November 19:** California Telehealth Policy Coalition and E-Consult Workgroup Annual Meeting | Sacramento, CA | Register here
- **December 4-5:** ASTP/ONC 2024 Annual Meeting | Washington D.C. | Register here