Final Report of the Roundtable on Artificial Intelligence in Healthcare

Harnessing Emerging Technologies to Transform Healthcare in the 21st Century

Major Themes and Recommendations

June 05, 2024

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I. Executive Summary

UW Health, the integrated health system of the University of Wisconsin, and Epic co-hosted a Roundtable on Artificial Intelligence in Healthcare on June 5, 2024, in Washington, DC. The roundtable was the first of its kind to examine artificial intelligence (AI) topics through the lens of healthcare delivery and the patient/provider experience.

To ensure robust discussion, we brought together thought leaders from the federal government, healthcare organizations, academic medical centers, health insurers, and tech companies. Our goal was to identify strategies necessary for successful AI implementation in healthcare to help policymakers shape effective laws and regulations in support. Several key themes emerged during our discussions:

Al's potential to address workforce shortages in healthcare

Participants agreed that AI can augment clinical and administrative roles, enhance efficiency, and allow organizations to strengthen the "face to face" human interactions necessary for high quality care while integrating new technologies. They emphasized the need for strategic AI adoption, focusing on outcomes rather than outputs, and discussed specific AI use cases such as real-time patient monitoring and automated data entry.

The critical need for transparency as AI reaches the point of care

Healthcare organizations implementing AI must work to build trust in the technology with both patients and providers, inform patients when AI is used in care delivery, and ensure transparency on data use by external providers. Participants agreed that successful AI use cases must focus on alleviating existing stressors in the healthcare workforce. Healthcare staff should understand that their employers' goal is to use AI to support them, not replace them.

Ensuring access to AI in healthcare regardless of the patient's location

To be truly transformative, AI and its benefits must be accessible in rural and underserved areas. Participants agreed on the importance of infrastructure development and technical assistance for equitable AI adoption. The discussion also covered the need for flexible definitions and governance frameworks for AI based on risk rather than the technology itself.

Fostering local validation to ensure AI's efficacy across diverse patient populations

Participants expressed clear support for local validation of AI models, complemented by overarching federal policies. Healthcare organizations serve varying populations based on location, focus, and many other factors, which limits the effectiveness of validation based on "generic" patient pools. AI adoption methodologies must include validating models against each organization's unique set of patient data.

As background for discussions, Dr. Micky Tripathi of the Office of the National Coordinator for Health Information Technology (ONC) outlined several key Health and Human Services initiatives, such as ongoing AI activities at the National Institutes of Health and the Food and Drug Administration. He also commented on the need to expand the Food and Drug Administration's (FDA) capacity to review AI applications and the upcoming requirement for transparency of AI tools in the electronic health record (EHR) system by January 2025.

II. Introduction and Background

Al has emerged as a transformative force in healthcare. As more organizations incorporate Al into their operations, federal policymakers have begun work on legislation and regulations to ensure appropriate oversight.

President Biden's <u>Executive Order on the Safe, Secure, and Trustworthy Development and Use of</u> <u>Artificial Intelligence</u>, seeks to advance a coordinated, federal government-wide approach to the safe and responsible use of AI by recommending comprehensive regulatory principles and policies and directing several agencies to develop standards and technical guidelines. In the wake of the executive order, several proposals have been introduced to meet the burgeoning need for regulatory oversight.

The Senate AI working group unveiled a <u>Roadmap for Artificial Intelligence Policy</u>, outlining key policy priorities for the 118th Congress, for example.

For AI efforts to succeed, it is crucial that policymakers and healthcare providers collaborate to ensure patient and workforce dynamics receive appropriate consideration. The Roundtable on Artificial Intelligence in Healthcare served as a provider-led platform for a diverse group of stakeholders to identify the critical issues that should help shape future policy initiatives related to AI in healthcare.

The roundtable was unique in that unlike many other discussions that have focused on the technological aspects of AI, we examined AI through the lens of healthcare delivery and the policy mechanisms needed to drive equity and access. By bringing together healthcare providers, payers, policy experts, and other key stakeholders, the roundtable identified best practices for integrating AI into the care process, reviewed current and pending policies, and developed consensus recommendations to establish essential guardrails for AI implementation in healthcare.

Participants explored how AI can enhance access to care, expedite healthcare delivery, and address disparities in underserved communities while reflecting on potential pitfalls that must be addressed in regulating this transformative technology. The roundtable included discussions on responsible AI adoption, understanding AI's limitations, infrastructure investment, and addressing the healthcare industry's burnout crisis.

As next steps, participants plan to distill and circulate their recommendations among policymakers and key healthcare AI stakeholders to help support a successful adoption that improves care outcomes and efficiency while delivering a positive experience for patients and providers.

III. Primary Discussion Themes

Patient Care and Experience

Workforce

The National Center for Health Workforce Analysis (NCHWA) projects significant shortages in the healthcare workforce through 2036: 139,940 total physicians (including 68,020 primary care physicians and 6,610 OB-GYNs), 337,970 registered nurses, and over 200,000 mental and behavioral health professionals. Al has significant potential to help healthcare organizations address workforce shortages by augmenting existing processes and enhancing efficiency.

Participants agreed on AI's potential to allow healthcare professionals to dedicate more time to patient care with a reduced administrative burden. While human oversight remains essential, participants concluded that increasing AI's role would positively impact patient care. Many in the healthcare space are new to AI and need time, tools, and resources to integrate it and use it to its full potential. Healthcare institutions should collaborate to train workers to implement AI into their work. Above all, healthcare providers should ensure AI systems prioritize patient care to combat common concerns that employers view AI as a tool for replacing human workers.

Supplementing Diagnostic Care

There was broad consensus on AI's ability to handle routine administrative tasks, such as documentation and patient monitoring. This allows healthcare professionals to focus on more complex and patientcentered activities, which improves operational efficiency and quality of care. Healthcare organizations are already using AI to reduce the need for manual data entry, draft responses to patient inquiries, and aid in cross-team communication. In radiology, algorithms aid in image analysis, significantly enhancing diagnostics and treatment planning.

Al is also assisting in real-time monitoring of patient conditions, which optimizes clinical staff use and reduces burnout. Healthcare organizations use Al to generate clinical deterioration alerts and unified notifications about patient status, facilitating holistic and prompt care interventions. Al models have been employed in predictive analytics to foresee risks such as geriatric falls, enabling preemptive interventions and timely referrals for specialty care.

These applications demonstrate AI's potential to transform healthcare by improving efficiency, accuracy, and patient outcomes. They also provide examples of innovations to adopt as stakeholders explore avenues to augment diagnostic care. Participants agreed that universally implementing such practices could help provide more specialized care in rural and underserved communities.

Further Integration into Clinical Work

There was enthusiasm over deeper integration of AI into clinical workflows, which will improve overall efficiency and reduce the manual workload on healthcare providers. This integration will streamline processes to allow more time for direct patient care and enhance clinical decision-making by offering data-driven insights, leading to more informed treatment plans and improved patient outcomes. In public health, AI will be pivotal for empowering patients with tools to manage personal health data for better health maintenance and disease prevention. The technology's ability to analyze longitudinal



patient data will detect trends and predict health issues early, enabling preventive care and timely interventions. Integrating AI into telehealth services will enhance virtual diagnostics and patient monitoring, making remote healthcare more effective and accessible.

Participants cautioned, however, that AI's use for complex tasks will require more extensive evaluation and input from the healthcare community to determine feasibility. Several voiced concerns that the inappropriate application of AI could exacerbate existing issues. Discussions drew parallels between excitement over the transformative potential of AI to similar enthusiasm over EHR systems more than 15 years ago. Healthcare organizations learned that incorrectly implemented EHRs risked perpetuating bad practices.

Participants emphasized the importance of early engagement with end users to ensure successful AI adoption and prioritize patient-centered solutions over enterprise-focused ones. AI should improve workflows by increasing efficiency in complicated tasks and minimizing bureaucratic burdens. Addressing behavioral changes among providers and turning data into actionable insights are essential for success.

Addressing Gaps in Data

Participants reviewed concerns that applying AI inappropriately could set back efforts to improve equity in healthcare access and quality. Current AI models often lack transparency, especially in 510K summaries. Pediatric care experts noted that pediatric data is often excluded from AI models. This exclusion has resulted in gaps in AI performance in pediatric radiology, where algorithms trained primarily on adult cases struggle to accurately diagnose and predict outcomes for children.

These challenges underscore the necessity for inclusive AI systems representing diverse patient populations. Local validation—empowering healthcare organizations to test AI models on their own patient data rather than mandating centralized and generic validation—will be essential. At the same time, participants noted that differential performance based on the data AI models are trained on could exacerbate existing disparities if not properly managed.

Participants reviewed the specific challenges faced by rural hospitals in adopting AI technologies, emphasizing the need to support these facilities with cost-effective and accessible AI solutions to prevent widening technological gaps. A public health approach to AI, involving leveraging low-cost tools to ensure accessibility regardless of insurance barriers and promoting open-sourcing of best practices to democratize access, will help address these challenges.

The conversation underscored the importance of consent and patient involvement in AI implementation. While physicians are adopting AI, ensuring patients understand and accept its benefits, such as more accurate charts and efficient provider interactions, is crucial for success. Participants noted high consent rates when patients were well-informed about AI benefits. As policymakers consider AI regulations, participants advocated for reviewing the <u>AI Bill of Rights for Patients</u>, which includes draft recommendations from patient advocates.

Role of Government in Regulation

To enable effective regulation of AI in healthcare, regulatory bodies must have the necessary authority to act under legislative frameworks established by Congress. With this authority in place, policymakers and government agencies must approach new regulations with a thorough understanding of AI's impact on patient care. This will allow them to establish appropriate guardrails to both foster innovation and mitigate unintended consequences. Participants agreed on many areas where regulatory support is needed. New and updated regulations should:

- Encourage AI innovation and ensure access to AI-driven tools regardless of location. Open-source tools and best practices should be available, especially in low-resource settings.
- Ensure AI is used to empower patients, improve public health, and transform care delivery rather than reinforce existing processes.
- Help shape the development of AI tools that ensure equitable access and address disparities in quality of care, particularly for rural and underserved communities.
- Foster local validation of AI models. Participants agreed that the contextual and regional variations in AI model outcomes necessitate local validation to ensure equitable and accurate output tailored to specific patient populations and healthcare workflows. This validation is especially critical for widespread adoption outside of major metropolitan areas and top clinical centers.
- Extend beyond the patient-provider relationship to encompass all interactions involving patient data, recognizing that any data within a medical setting has clinical implications. As healthcare expands beyond traditional settings into at-home care, telehealth, and community-based organizations, regulatory frameworks must adapt.
- Provide targeted investment and support to ensure AI benefits reach rural and under-resourced settings, such as federal incentives to encourage broader adoption of AI technologies. Establishing registries for AI tools can facilitate tracking and validation across different settings, while open-source tools can promote innovation and local validation, ensuring equitable access to AI benefits.

Definitions of AI

Participants stressed the importance of consistency in defining AI across domestic and international contexts. AI is a dynamic concept that encompasses many facets of computer science. Tasks that are now categorized as data science were once considered part of AI. Over time, AI's definition has evolved from basic statistical methods to encompass more advanced and distinct technologies. Aligning definitions and sub-definitions globally will promote uniformity in regulatory frameworks and ensure coherence in AI governance.

Participants emphasized that governance should prioritize understanding the use case and associated risks rather than adhering strictly to rigid definitions. Frameworks developed for medical devices can be

adapted to include specific risks and safety considerations associated with AI. There is a delicate balance between maintaining evaluation stability and integrating the latest technological advancements. Defining AI based on its risk level is seen as a pragmatic approach, guiding the implementation of appropriate regulatory and safety measures.

IV. Path Forward

The roundtable highlighted AI's significant potential to revolutionize healthcare delivery and enhance patient outcomes. Participants stressed the importance of balancing AI's benefits with ethical considerations, patient engagement, and robust regulatory frameworks. Collaboration among stakeholders—industry, government, and patients—will be essential in many areas:

Workforce Support

Plan for early engagement with end users to boost adoption and ensure AI solutions enhance patient care quality, safety, and privacy. Initiatives that reduce administrative burden and allow more time to be focused on patient care such as patient inquiry responses, documentation, personalized health tips, and remote monitoring should take priority.

Local Validation

Advocate for policies that support and expand local validation processes while preventing redundant efforts. Put effective program monitoring in place to sustain early successes and help organizations understand how to adjust strategies as needed to optimize outcomes and ensure equity.

Data Privacy

It is imperative to ensure a balance between AI's benefits and robust patient data privacy measures. Stakeholders should review existing patient and data privacy protections, determine how they apply to AI-driven tools, and work with policymakers on updates and new regulations as needed.

Leveled Playing Field

Structure a public health approach to AI to ensure its benefits are available in rural and low-resource settings. The industry must address disparities in AI investment due to existing payment structures and embrace flexible governance frameworks that incorporate diverse stakeholder perspectives.

Balance Between Innovation and Safety

Advocate for expanding the FDA's capacity to review AI applications and establish post-market regulatory framework to enforce transparency mandates enacted through recent Department of Health and Human Services (<u>HHS) regulations</u>. Participants agreed that structures should be put in place to ensure providers have the information on their AI-enabled tools to comply with HHS' Office of Civil Rights (OCR) rules.

Government Alignment and Strategic Planning

Encourage ongoing inter-agency communication on AI advancements and help ensure healthcare organizations can access comprehensive information about their AI-enabled tools to comply with OCR rules. Discussions favored completing the HHS AI Strategic Plan and the appointment of a Chief AI Officer to guide future initiatives.

Clear Guardrails Surrounding AI Definitions

Establish clear and transparent definitions of AI that are risk-based, fostering trust and understanding among stakeholders. Participants recommended a flexible and evolving approach, integrating statistical and workflow modeling considerations and avoiding rigid definitions.

Appendix A: List of Participants

Alan Kaplan (Host)

CEO, UW Health

Chero Goswami (Moderator) Chief Information & Digital Officer, UW Health

Seth Hain (Moderator)

Senior Vice President of Research and Development, Epic

Micky Tripathi (Speaker)

National Coordinator for Health Information Technology, HHS ONC Chief Artificial Intelligence Officer (Acting), HHS ONC

Suresh Balu

Associate Dean for Innovation and Partnership, Duke School of Medicine Program Director, Duke Institute for Health Innovation

Skylar Borchardt

Legislative Director, Office of Congresswoman Angie Craig (D-MN-02)

Lois Brooks

Chief Information Officer & Vice Provost for Information Technology, UW-Madison

Jeff Cribbs

Vice President & Distinguished Analyst, Gartner Healthcare

Joe Depa

Chief Data & Analytics Officer, Emory University

Keith Dreyer

Chief Data Science Officer, Mass General Brigham

Jackie Gerhart

Physician & Vice President of Clinical Informatics, Epic

Mike Goodman

Assistant Vice President of Generative AI & Innovation, Emory University

Cecily Hahn

Senior Legislative Council, Office of Senator Tammy Baldwin (D-WI)

Brenton Hill

Head of Operations and General Counsel, Coalition for Health AI

Jeffrey Kim

Chief Medical Information Officer, VCU Health

Kristina Ko

Vice President of Government Relations & Public Policy and Chief Government Affairs Officer, Corewell Health

Frank Liao

Senior Director Digital Health and Emerging Technologies, UW Health

Zachary Lipton

Chief Scientific and Technology Officer, Abridge

Peter Marks

Vice President & Chief Information Officer, WakeMed

Paul Meyer

Co-Founder & CEO, Smart Health Network PBC

Smit Patel

Director, Head of AI, Digital Medicine Society (DiMe)

Donna Roach

Chief Information Officer, U of Utah Hospital

Colin Rom

Public Policy Lead for Bio and Health, Andreessen Horowitz

Christopher Sharp

Chief Medical Information Officer, Stanford University Medical Center



Appendix B: Roundtable Agenda

9:30 AM Arrive at Venue

10:00 AM	Welcome and Opening Remarks Introduction of Speakers: Cherodeep Goswami, UW Health Speaker Opening Remarks: Dr. Alan Kaplan, CEO of UW Health, and Dr. Micky Tripathi National Coordinator for Health Information Technology and Acting Chief Artificial Intelligence Officer of HHS
10:15 AM	Discussion Block 1: Patient Care and Experience Moderators: Cherodeep Goswami, UW Health, and Seth Hain, Epic
11:15 AM	Break
11:30 AM	Discussion Block 2: Role of Government in Regulation Moderators: Cherodeep Goswami, UW Health, and Seth Hain, Epic
12:30 PM	Lunch and Roundtable Discussion on Path Forward Moderators: Cherodeep Goswami, UW Health, and Seth Hain, Epic
1:15 PM	Closing Remarks Speakers: Seth Hain, Epic, and Dr. Alan Kaplan, CEO, UW Health

1:30 PM Adjourn

Appendix C: Definitions of AI

Varying definitions of artificial intelligence are discussed at the U.S. federal level as well as internationally. These include:

A: a machine-based system that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments. Different AI systems vary in their levels of autonomy and adaptiveness after deployment. (OECD)

B: a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action. (15 U.S.C. 9401(3))

• This is referenced in the AI Foundation Model Transparency Act of 2023 (H.R. 6881), the Health Technology Act of 2023 (H.R. 206), the Future of Artificial Intelligence Innovation Act of 2024 (S. 4178), and the Chips and Sciences Act (H.R. 4346).

C: (1) Any artificial system that performs tasks under varying and unpredictable circumstances without significant human oversight, or that can learn from experience and improve performance when exposed to data sets. (2) An artificial system developed in computer software, physical hardware, or other context that solves tasks requiring human-like perception, cognition, planning, learning, communication, or physical action. (3) An artificial system designed to think or act like a human, including cognitive architectures and neural networks. (4) A set of techniques, including machine learning, that is designed to approximate a cognitive task. (5) An artificial system designed to act rationally, including an intelligent software agent or embodied robot that achieves goals using perception, planning, reasoning, learning, communicating, decision making, and acting. (John S. McCain National Defense Authorization Act for Fiscal Year 2019)

• This is referenced in the Transparent Automated Governance Act (H.R. 6886), the Federal Al Governance and Transparency Act (H.R. 7532), the Al Leadership to Enable Accountable Deployment Act (S. 2293), the Al Leadership Training Act (S. 1564), and the Transparent Automated Governance Act (S. 1865).

D: an engineered system that (a) generates outputs, such as content, predictions, recommendations, or decisions for a given set of objectives; and (b) is designed to operate with varying levels of adaptability and autonomy using machine and human-based inputs. (Artificial Intelligence Research, Innovation, and Accountability Act of 2023)

E: an engineered system that (a) generates outputs, such as content, predictions, recommendations, or decisions for a given set of objectives; and (b) is designed to operate with varying levels of adaptability and autonomy using machine and human-based inputs (NIST AI Risk Management Framework 1.0)

Appendix D: Additional Resources

Previous Federal and State-Level Legislative and Regulatory Proposals for AI in Healthcare

Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence

In October 2023, the Biden Administration released an executive order that aims to advance a coordinated, federal government-wide approach to the safe and responsible use of AI. It set forth various regulatory principles and policies and directed several agencies to develop standards and technical guidelines. The executive order focused on eight key policy areas: new standards for AI safety and security; protecting Americans' privacy; advancing equity and civil rights; standing up for consumers, patients, and students; supporting workers; promoting innovation and competition; advancing American leadership abroad; and ensuring responsible and effective government use of AI. Specific to healthcare, the Administration calls for advancing the responsible use of AI in healthcare.

A Roadmap for Artificial Intelligence Policy in the U.S. Senate

Released in May 2024 and assembled by the bipartisan Senate AI Working Group (Mike Rounds, R-SD, Todd Young, R-IN, Chuck Schumer, D-NY, and Martin Heinrich, D-NM), the Roadmap summarizes the Working Group's findings following nine AI Insight Forums with over 150 experts. It lays out several policy priorities they believe merit consideration in the 118th Congress. These areas of interest include: supporting U.S. innovation in AI; AI and the workforce; high-impact uses of AI; elections and democracy; privacy and liability; transparency, explainability, intellectual property, and copyright; safeguarding against AI risks; and national security.

The Roadmap also contained healthcare-specific recommendations, including:

- Implementing legislation that both furthers the deployment of AI in healthcare and implements appropriate guardrails and safety measures to protect patients.
- Supporting the NIH in the development and improvement of AI technologies, with a focus on data governance, accessibility, and privacy.
- Ensuring that HHS has the proper tools to weigh the benefits and risks of AI-enabled products so that it can provide a predictable regulatory structure for product developers.
- Providing transparency for providers and the public about the use of AI in medical products and clinical support services, including the data used to train the AI models.
- Promoting innovation of AI systems that meaningfully improve health outcomes and efficiencies in healthcare delivery, including examining CMS' reimbursement mechanisms as well as guardrails to ensure accountability, appropriate use, and broad application of AI across all populations.



Colorado SB24-205: Colorado Artificial Intelligence Act

In May 2024, Colorado Governor Jared Polis signed into law Colorado Senate Bill 24-205 (SB 205), a comprehensive state law regulating AI use in the private sector, including healthcare. This bill makes Colorado the first state in the nation to address the use of "high-risk" AI systems and establishes a range of detailed requirements for AI developers and deployers. The bill mandates disclosures about high-risk AI systems, requires developers and deployers to tackle algorithmic discrimination, and enhances protections when high-risk AI systems make decisions that impact consumers. For healthcare, it does create exemptions for technology complying with ONC standards, research supporting FDA product applications, and HIPAA-covered providers using non-high-risk AI systems for recommendations. The law will go into effect on February 1st, 2026.