ConnectedHealthInitiative

May 24, 2024

The Honorable Ami Bera
Cofounder
Health Care Innovation Caucus
Washington, District of Columbia 20515

RE: Request for information on the state of AI in healthcare

Dear Representative Bera:

The Connected Health Initiative (CHI) thanks you for the opportunity to contribute to your request for information on the state of artificial intelligence (AI) in healthcare. As AI continues to evolve, it will play an important role in several aspects of healthcare delivery and administration. Your interest in understanding the field's current use of the technology will help inform policy decisions to ensure that AI can be used responsibly and appropriately while still ensuring the safety of patients and providers.

CHI is the leading effort by stakeholders across the connected health ecosystem to responsibly encourage the use of digital health innovations and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled American healthcare system. For more information, see www.connectedhi.com.

CHI has worked to proactively address health AI governance and policy issues based on consensus views that span the healthcare sector, from technology developers to providers to patients. We urge your consideration of a number of policy and governance recommendations developed based on this consensus, which we expand on below and which are also appended to this letter:

- CHI's *Health AI Policy Principles*, a comprehensive set of recommendations across key areas that should be addressed by any policymaker considering AI's use in healthcare (available at https://bit.ly/3m9ZBLv);

- CHI's *Health AI Roles and Interdependencies Framework*, which describes the health AI value chain, defining actors and describing roles for ensuring safety and efficacy as well as the interdependencies between these actors (https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf);

- CHI's *Good Machine Learning Practices for FDA-Regulated AI*, a risk-based approach to benefit the Food and Drug Administration (FDA) as it addresses both locked and continuously-learning AI systems that meet the definition of a medical device (https://bit.ly/2YaYljk); and

- CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*, comprehensive recommendations on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (https://bit.ly/3n36WO5).

Your attention to health AI in this inquiry takes place at a critical time, when a coordinated effort across both executive and independent agencies is deeply needed. Already, numerous regulatory agencies, some cross-sectoral and others sector-specific, are considering or advancing regulatory proposals that would take starkly different approaches to AI accountability. Some of these proposals are poised to put significant hurdles in place for the development and use of AI through one-size-fits-all approaches that have nominal public benefit at best,[1] in misalignment with other leading U.S. government efforts such as those of the National Institute of Standards and Technology (NIST)[2]. In some other cases, AI regulatory proposals are being developed based on speculative and undemonstrated harms.[3] We urge you to ensure a harmonized and risk-based approach to AI governance. While thoughtful restrictions are important, especially in areas like data privacy, many agencies are already working to meaningfully improve healthcare through AI applications. We must continue to foster innovation while mitigating the risks of AI technologies.

As we learn more about the applications of AI technologies to healthcare, it is important to take a measured approach. Many agencies have existing regulatory authority and oversight mechanisms that apply to AI without Congressional changes. For example, the FDA's current process for evaluating and regulating these products works well to impose necessary guardrails on the implementation of AI in health devices and software. They have successfully evaluated many new tools, devices, and software applications that use AI, approving many that conform to their standards regarding safety and usage. One of the keys of the FDA process to evaluating AI products is their risk-based approach. AI has the potential to affect nearly all aspects of healthcare, but not all AI applications have an equal impact on patient health, data security, or clinical outcomes. Appropriately, the FDA treats technologies with higher risk to personal data, health outcomes, and other sensitive areas differently than technologies or applications that deal only with scheduling functions or other low-risk areas—areas that can be especially difficult for smaller practices. This type of approach works to minimize negative patient outcomes while fostering growth and innovation in the sector. Congress should encourage similar risk-based frameworks in other areas to ensure continued access to lower-risk AI applications while thoughtfully evaluating higher-risk innovations.

Many AI applications in healthcare rely on standardized approaches to software and hardware safety/risk management and interoperability. Congress should support the development of international technical standards on health AI and use these standards to support regulations. The development of such standards enables interoperability between health devices and electronic health records (EHRs), as well as between different health devices. AI tools benefit from clarity and consistency through use of standards. For example, ISO 42001 is an international management system standard that provides a framework to address and control

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[1] Nondiscrimination in Health Programs and Activities, 87 FR 47824 (Aug. 4, 2022); the App Association's Connected Health Initiative detailed views on this HHS OCR proposal are included in this comment as **Appendix B**.

[2] https://www.nist.gov/itl/ai-risk-management-framework.

[3] Trade Regulation Rule on Commercial Surveillance and Data Security, 87 FR 51273 (Aug. 22, 2022); App Association views provided to the Federal Trade Commission in response to its Advanced Notice of Proposed Rulemaking are available at https://www.regulations.gov/comment/FTC-2022-0053-1089.

AI-related risks,[4] while ISO/IEC 23894 provides guidance on AI risk management.[5] Such standards can and should provide a foundation for U.S. AI regulation that ensures safety and efficacy while ensuring thoughtful design and patient/consumer safety. Such standards are also built into NIST's voluntary AI Risk Management Framework,[6] which CHI supports and urges for alignment with. Furthermore, such standards provide the technical underpinnings for conformity assessment requirements such as testing, validation or certification.

As agencies work to evaluate AI devices and tools, transparency in aspects of the development will be important for accurate evaluation and approval. However, transparency should not compromise the intellectual property or trade secrets of the entity developing an AI tool. Protecting intellectual property will help encourage innovation in health AI, which will lead to more effective healthcare, less physician burnout, and better access to services. Evaluators and overseers should also consider the reported steps taken by the developer to promote transparency and responsible use of their products.

AI can be a helpful tool to healthcare providers as well as their patients. We see AI used in doctor's office, for example, to minimize administrative burdens and streamline providers' notetaking and EHR intake. This use of AI is incredibly helpful to primary care providers who are increasingly burdened with excessive tasks that limit their time spent on patient care. Outside of the clinical environment, AI can help pharmacies fill prescriptions faster, anticipate shortages and needs, and convey out-of-pocket estimates to patients. AI has also been used to support drug discovery, including via in-depth genomic analyses to help tailor medicines to the specific needs of patients. These are just a few of the ways that AI currently impacts healthcare delivery. It improves outcomes, cuts costs, and streamlines service delivery.

Building on the above, we urge you, in your capacity as both co-founder of the Healthcare Innovation Caucus and member of the bipartisan House Task Force on Artificial Intelligence, to ensure that AI systems deployed in healthcare advance the "Quadruple Aim"[7] by improving population health; improving patient health outcomes and satisfaction; increasing value by lowering overall costs; and improving clinician and healthcare team well-being. These are areas where we are already seeing the potential AI systems have to positively impact the current healthcare system.

> **Improving Population Health Management:** AI-enabled tools offer great promise in overcoming the challenges faced by clinicians, health systems, health plans, and public health officials working to advance population health management and public health. AI-enabled tools, for example, are able to process massive and disparate data sources to provide public health officials, health care systems, and providers essential and actionable data rapidly related to assist with more timely and accurate population level disease surveillance and assessments of disparities and health care resource distribution.

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[4] https://www.iso.org/management-system-standards.html.
[5] https://www.iso.org/standard/77304.html.
[6] https://www.nist.gov/itl/ai-risk-management-framework.
[7] Bodenheimer T, Sinsky C. From triple to quadruple aim: care of the patient requires care of the provider. *Ann Fam Med*. 2014;12(6):573-576.

Population health[8] management has long been viewed as the essential ingredient to improve overall health outcomes and arrest rising health care costs. Population health management involves aggregation and analysis of huge amounts of data from divergent sources, something that can be potentially streamlined through robust and powerful AI systems.

As more systems are created and deployed, the opportunity for AI to help improve healthcare outcomes is significant, with estimates suggesting outcomes could be improved by 30-40 percent.[9]

Improving Patient Experience, Satisfaction, and Outcomes: One of the more significant critiques of healthcare systems around the world is that they fail in many respects to meet patients' expectations around access to care, ease of use, and care continuity and coordination.

All too often, patients are forced to make multiple visits, shuffling between a general practitioner and a specialist. With the ability to replicate specialist-level expertise at the frontlines of care, AI-enabled tools will reduce paperwork burdens, center care around where the patient is located, and enhance the ability to manage and understand how to sustain health or manage a disease. Services that increasingly can be enhanced and improved with AI systems will provide patients and their health care teams with timely, essential information, and ongoing support that is not currently available.

With people over the age of 65 representing an increasing percentage of the population, AI systems will be essential for human caregivers and clinicians to extend their reach and coverage of an ever-growing population of patients.

Reducing Healthcare Costs: Countries around the world struggle with both rising costs and absolute costs of providing healthcare to their citizens. Nations spend between roughly 6 percent and 18 percent of their gross domestic product (GDP) and many have seen the share of GDP devoted to healthcare costs sharply rise over the last three decades.[10] The situation is unsustainable, and, in many countries, the problem will only get more acute as populations age and average life expectancy continues to rise. A huge amount of data is available today for collection and utilization in timely prevention and treatment decisions that would result in massive cost savings, but that data currently usable, but can be found in electronic health record (EHR) systems.

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[8] Defined as "an approach [that] focuses on interrelated conditions and factors that influence the health of populations over the life course, identifies systematic variations in their patterns of occurrence, and applies the resulting knowledge to develop and implement policies and actions to improve the health and well-being of those populations." Kindig, D. and Stoddart, G. What Is Population Health? American Journal of Public Health, 93, 380-383 (2003).

[9] Nicole Lewis, Artificial Intelligence to play key role in population health, Medical Economics (2017) (available at http://www.medicaleconomics.com/medical-economics-blog/artificial-intelligence-play-key-role-population-health)

[10] Henry J Kaiser Family Foundation, Snapshots: Health Care Spending in the United States & Selected OECD Countries (2011); Bradley Sayer and Cynthia Cox, How does health spending in the U.S. compare to other countries?, Kaiswer Family Foundation (2018).

Healthcare experts see enormous promise in AI to more accurately capture and leverage the range of health data available, with estimates suggesting AI applications can create $150 billion in annual savings for the United States healthcare economy by 2026.[11] This savings estimate includes only the top 10 AI scenarios, such as assisted surgery, virtual nursing assistants, and administrative workflow assistance, etc.

On a worldwide basis, healthcare administrative costs (e.g., billing) are a continuing challenge. The administrative costs of the U. S. health care system are estimated to be 31 percent of total healthcare expenditures.[12] AI's potential to help us address spiraling costs in healthcare is very real, and it is already showing returns today.

Improving Clinician and Healthcare Team Experience and Satisfaction: Among clinicians and the extended health care team, the growing administrative and paperwork demands coupled with compounding rates of new medical knowledge and data generation are driving records levels of burn-out and dissatisfaction. AI-enabled tools can and should be deployed to drastically improve clinician and healthcare team satisfaction using tools that help clinicians and the health care team to more quickly screen, diagnose, treat, and effectively monitor patients and remove time-consuming and often mundane tasks.

To build on the groundbreaking progress AI is already offering across healthcare use cases, U.S. government can meet this goal by aligning its policies, enforcement actions, guidance, and other communications with CHI's comprehensive health AI policy principles:

Quality Assurance and Oversight: Policy frameworks should utilize risk-based approaches to ensure that the use of AI in healthcare aligns with recognized standards of safety, efficacy, and equity. Providers, technology developers and vendors, health systems, insurers, and other stakeholders all benefit from understanding the distribution of risk and liability in building, testing, and using healthcare AI tools. Policy frameworks addressing liability should ensure the appropriate distribution and mitigation of risk and liability. Specifically, those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so. Some recommended guidelines include:

- Ensuring AI in healthcare is safe, efficacious, and equitable.

- Ensuring algorithms, datasets, and decisions are auditable and when applied to medical care (such as screening, diagnosis, or treatment) are clinically validated and explainable.

- AI developers should consistently utilize rigorous procedures and must be able to document their methods and results.

- Those developing, offering, or testing healthcare AI systems should be required to provide truthful and easy to understand representations regarding

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[11] Accenture, Artificial Intelligence: Healthcare's New Nervous System (2017)

[12] http://www.pnhp.org/publications/nejmadmin.pdf

intended use and risks that would be reasonably understood by those intended, as well as expected, to use the AI solution.

- Adverse events should be timely reported to relevant oversight bodies for appropriate investigation and action.

Thoughtful Design: Policy frameworks should require design of AI systems in healthcare that are informed by real-world workflow, human-centered design and usability principles, and end-user needs. Also, AI systems should help patients, providers, and other care team members overcome the current fragmentation and dysfunctions of the healthcare system. AI systems solutions should facilitate a transition to changes in care delivery that advance the quadruple aim. The design, development, and success of AI in healthcare should leverage collaboration and dialogue between caregivers, AI technology developers, and other healthcare stakeholders in order to have all perspectives reflected in AI solutions.

Access and Affordability: Policy frameworks should ensure AI systems in healthcare are accessible and affordable. Significant resources may be required to scale systems in healthcare and policymakers must take steps to remedy the uneven distribution of resources and access. There are varied applications of AI systems in healthcare such as research, health administration and operations, population health, practice delivery improvement, and direct clinical care. Payment and incentive policies must be in place to invest in building infrastructure, preparing personnel and training, as well as developing, validating, and maintaining AI system with an eye toward ensuring value. While AI systems should help transition to value-based delivery models by providing essential population health tools and providing enhanced scalability and patient support, in the interim payment policies must incent a pathway for the voluntary adoption and integration of AI systems into clinical practice as well as other applications under existing payment models.

Research: Policy frameworks should support and facilitate research and development of AI in healthcare by prioritizing and providing sufficient funding while also ensuring adequate incentives (e.g., streamlined availability of data to developers, tax credits) are in place to encourage private and non-profit sector research. Clinical validation and transparency research should be prioritized and involve collaboration among all affected stakeholders who must responsibly address the ethical, social, economic, and legal implications that may result from AI applications in healthcare. Further, public funding and incentives should be conditioned on promoting the medical commons in order to advance shared knowledge, access, and innovation.

Ethics: Given the longstanding, deeply rooted, and well-developed body of medical and biomedical ethics, it will be critical to promote many of the existing and emerging ethical norms of the medical community for broader adherence by technologists, innovators, computer scientists, and those who use such systems. Healthcare AI will only succeed if it is used ethically to protect patients and consumers. Policy frameworks should:

- Ensure AI in healthcare is safe, efficacious, and equitable.

- Ensure that healthcare AI solutions align with all relevant ethical obligations, from design to development to use.

- Encourage the development of new ethical guidelines to address emerging issues with the use of AI in healthcare, as needed.

- Ensure consistency with international conventions on human rights.

- Ensure that AI for health is inclusive such that AI solutions beneficial to patients are developed across socioeconomic, age, gender, geographic origin, and other groupings.

- Reflect that AI for health tools may reveal extremely sensitive and private information about a patient and ensure that laws protect such information from being used to discriminate against patients.

Modernized Privacy and Security Frameworks: While the types of data items analyzed by AI and other technologies are not new, this analysis provides greater potential utility of those data items to other individuals, entities, and machines. Thus, there are many new uses for, and ways to analyze, the collected data. This raises privacy issues and questions surrounding consent to use data in a particular way (e.g., research, commercial product/ service development). It also offers the potential for more powerful and granular access controls for patients. Accordingly, any policy framework should address the topics of privacy, consent, and modern technological capabilities as a part of the policy development process. Policy frameworks must be scalable and assure that an individual's health information is properly protected, while also allowing the flow of health information. This information is necessary to provide and promote high-quality healthcare and to protect the public's health and well-being. There are specific uses of data that require additional policy safeguards, i.e., genomic information. Given that one individual's DNA includes potentially identifying information about even distant relatives of that individual, a separate and more detailed approach may be necessary for genomic privacy. Further, enhanced protection from discrimination based on pre-existing conditions or genomic information may be needed for patients. Finally, with proper protections in place, policy frameworks should also promote data access, including open access to appropriate machine-readable public data, development of a culture of securely sharing data with external partners, and explicit communication of allowable use with periodic review of informed consent.

Collaboration and Interoperability: Policy frameworks should enable easier data access and use through creating a culture of cooperation, trust, and openness among policymakers, health AI technology developers and users, and the public.

Workforce Issues and AI in Healthcare: The United States faces significant demands on the healthcare system and safety net programs due to an aging population and a wave of retirements among practicing care workers. And lower birth rates mean that fewer young people are entering the workforce. Successful creation and deployment of AI-enabled technologies which help care providers meet the needs of all patients will be an essential part of addressing this projected shortage of care workers. Policymakers and stakeholders will need to work together to create the appropriate balance between

human care and decision-making and augmented capabilities from AI-enabled technologies and tools.

Bias: The risk of bias data as well as errors will remain one of the more pressing issues with AI systems that utilize machine learning techniques, in particular. In developing and using healthcare AI solutions, these data provenance and bias issues must be addressed. Policy frameworks should:

- Balance the identification, disclosure, and mitigation of bias with the need for access to databases and promotion of inclusion and diversity. Ensure that data bias does not cause harm to patients or consumers.

Education: Policy frameworks should support education for the advancement of AI in healthcare, promote examples that demonstrate the success of AI in healthcare, and encourage stakeholder engagements to keep frameworks responsive to emerging opportunities and challenges.

- Patients and consumers should be educated as to the use of AI in the care they are receiving.
- Academic/medical education should include curriculum that will advance healthcare providers' understanding of and ability to use health AI solutions. Ongoing continuing education should also advance understanding of the safe and effective use of AI in healthcare delivery

We appreciate the opportunity to share this input and to elaborate on our views further at your convenience.

Sincerely,

Brian Scarpelli
Executive Director
Connected Health Initiative