

ConnectedHealthInitiative

January 25, 2026

Washington State Artificial Intelligence Task Force
c/o Office of the Attorney General
800 Fifth Avenue
Seattle, WA 98104

RE: Comments of the Connected Health Initiative on the Washington State Artificial Intelligence Task Force's Interim Report

The Connected Health Initiative (CHI) writes to provide input to the Washington State Artificial Intelligence Task Force (AITF) on its December 2025-released Interim Report.

I. Statement of Interest and General Views on Healthcare AI

CHI is the leading multi stakeholder encouraging the use of digital health innovations and supporting 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 is a longtime active advocate for the increased use of new and innovative digital technologies in both the prevention and treatment of disease, and we appreciate the AITF's consistent collaboration as it studies the impact of AI and propose guidelines for its safe, ethical, and responsible use in Washington. AI products, services, and functions are radically improving the American healthcare system, represent the most promising avenue for improved care quality, reduced hospitalizations, avoidance of complications, and improved satisfaction, particularly for the chronically ill.

Already, AI-driven algorithmic decision tools and predictive analytics have substantial direct and indirect effects across consumer and enterprise contexts, but in the healthcare sector particularly. Across use cases and sectors, AI has incredible potential to improve consumers' lives through faster and better-informed decision-making, enabled by cutting-edge distributed cloud computing, with drug development being no exception. As AI systems, powered by streams of data and advanced algorithms, continue to improve services and generate new business models, the fundamental transformation of economies across the globe will only accelerate. Nonetheless, AI also has the potential to raise a variety of unique considerations for policymakers.

CHI appreciates the AITF's deliberating on and generating recommendations on safe, ethical, and responsible use in Washington. AI is already demonstrating clinical and operational value by delivering personalized, adaptive mental health support at scale, and as their algorithms and evidence base continue to mature, they are likely to further enhance care accessibility, precision, and patient engagement. We agree that, as these products further develop, new and/or novel risks may also follow, which make it critical for Washington's approach to evolve while enabling

innovation that supports public health. With rising demand for health services and limited access to qualified providers in the United States, such new technologies will help bridge care gaps, improving both outcomes and accessibility.

CHI has worked across its diverse stakeholder community for years to proactively address healthcare AI opportunities and challenges. CHI urges the DHAC to align its recommendations with the following, which are also appended to this comment letter:

- **CHI's Health AI Policy Principles [APPENDIX 1]**, a comprehensive set of recommendations on the areas that should be addressed by policymakers examining AI's use in healthcare, and how they should be addressed (<https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf>);
- **CHI's Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem [APPENDIX 2]**, a proposal on ways to increase the transparency of and trust in health AI tools, particularly for care teams and patients (<https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf>); and
- **CHI's Health AI Roles & Interdependency Framework [APPENDIX 3]**, which proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use; and suggests roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept (<https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf>).

II. CHI Input on Washington State Artificial Intelligence Task Force's Interim Report

a. Leveraging Existing Authorities

We urge the AITF to prioritize completing an initial comprehensive analysis of the state's existing laws and regulations pertaining to healthcare, data privacy, consumer protection, and technology governance. This foundational step would enable the AITF to identify where current frameworks, such as the Washington Health Care Authority's oversight of health data, HIPAA compliance requirements, and anti-discrimination statutes, can effectively mitigate demonstrated AI-related risks, including algorithmic bias, patient privacy breaches, and erroneous medical decisions. By mapping these intersections, the AITF can avoid proposing new regulations that overlap with or conflict with established ones, thereby promoting regulatory efficiency, reducing compliance burdens on healthcare providers and AI developers, and fostering innovation while safeguarding public health in Washington's evolving AI landscape.

b. Modernizing State Coverage and Reimbursement to Enhance Care Quality and Accessibility

Washington State should proactively advance responsible coverage and reimbursement policies for AI-enabled tools and services within its Apple Health (Medicaid) program. By integrating AI-driven solutions, such as predictive analytics for chronic disease management, remote physiologic monitoring, personalized care coordination, and decision support systems, Washington can augment clinical care delivery, enhance accessibility to timely and needed treatments for underserved populations, reduce clinician burnout, improve health outcomes, and lower overall costs in alignment with the quadruple aim of healthcare. This forward-looking approach would position the state as a leader in modernized, technology-supported Medicaid innovation, particularly for rural and low-income beneficiaries facing barriers to traditional in-person care.

To maximize impact and avoid fragmentation, these efforts should align closely with emerging federal policy processes at the Centers for Medicare & Medicaid Services (CMS), including the recently launched ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model. The ACCESS Model tests outcome-aligned payments in Original Medicare to expand access to technology-supported chronic care management, emphasizing flexible, clinician-guided use of digital tools, wearables, telehealth, and other innovations tied to measurable improvements in conditions like diabetes, hypertension, behavioral health, and cardio-kidney-metabolic diseases. By mirroring this risk-based, results-oriented framework, where reimbursement rewards demonstrated health gains rather than volume of services, Washington can harmonize its Medicaid policies with CMS's direction, facilitate potential future scaling or cross-payer adoption, and ensure that AI applications in Medicaid complement rather than conflict with federal advancements in technology-enabled care. This strategic alignment would encourage responsible AI deployment, promote interoperability, build stakeholder trust, and ultimately deliver more accessible, effective, and patient-centered healthcare across the state.

c. Leveraging a Risk-Based Approach to Trust and Governance

CHI recognizes that the wide variety of healthcare AI applications necessitates a targeted focus on those posing the greatest risk to patient safety, thereby addressing potential adverse effects without limiting advancement or access to lower-risk AI benefits. Mirroring existing regulatory distinctions, just as the FDA applies differentiated requirements to simple tools like tongue depressors versus complex, high-risk devices such as implantable cardioverter-defibrillators, Washington State's oversight frameworks should be proportional to the level of risk and context of use.

CHI endorses a risk-based framework for evaluation and ongoing monitoring throughout the entire product lifecycle as essential to maintaining the safety and effectiveness of healthcare AI technologies. This framework is key to ensuring AI systems remain trustworthy and perform reliably as they adapt within evolving clinical settings. A comprehensive lifecycle perspective reinforces the importance of continuous postmarket assessment through technologies designed to detect shifts in device performance. Such monitoring enables developers and users to identify issues promptly and apply necessary adjustments like retraining or recalibration. Regulatory flexibility is essential, especially regarding the degree of human oversight, which should be informed by empirical evidence, specific clinical settings, and the nature of the AI tool. For example, clinical experts may review imaging flagged by AI for suspicious areas rather than leaving final diagnostic decisions solely to the algorithm, while lower-risk AI functionalities might automate nonclinical tasks to enhance efficiency. This balanced approach promotes user trust and optimizes patient outcomes through effective human-AI collaboration.

Transparency and trust are central to clinician and patient engagement with AI technologies. Clear communication about the intended use, capabilities, and limitations of AI-enabled tools is necessary to support informed use and appropriate adoption. A comprehensive data governance framework underpins these efforts, emphasizing secure data environments, privacy-conscious training methodologies, and stringent control over protected health information. These practices not only meet regulatory expectations but also align with emerging global AI governance standards, highlighting the need for consistent and adaptable frameworks at federal and state levels.

CHI generally supports the Interim Report's recommendation to align with the National Institute of Standards and Technology's AI Risk Management Framework in the healthcare context, which emphasizes measurable, voluntary standards to manage risks like bias and privacy without stifling innovation or development. To strengthen its approach to AI in healthcare, CHI recommends that Washington State explicitly integrating the Quadruple Aim into the principles' application for healthcare AI, ensuring that systems are evaluated for their ability to demonstrably improve health outcomes, support the healthcare workforce, augment population health management, and lower costs.

d. Further Transparency Recommendations

CHI commends the Interim Report's focus on human oversight, bias mitigation, impact assessments, and independent audits, which echo CHI's advocacy for advancing transparency in the AI healthcare ecosystem. CHI recommends expanding this to encourage AI deployers to publicly disclose how their systems align with real-world clinical workflows, such as integrating with electronic health records or telehealth platforms, to prevent disruptions and ensure AI acts as a facilitator. Additionally, CHI urges the AITF to incorporate patient-centric transparency measures,

like providing accessible explanations of AI-influenced decisions directly to patients, to build trust and satisfaction in line with Quadruple Aim goals.

e. CHI Views on Evaluation Metrics

Regardless of whether AI is driven by classic machine learning methods or advanced generative models, assessing AI's effectiveness in healthcare must utilize evaluation metrics aligned with the clinical task at hand. Validation efforts need to reflect actual patient populations and case types to ensure clinical relevance and responsiveness to community health needs. While traditional diagnostic AI benefits from well-defined measures such as sensitivity and Area Under the Receiver Operating Characteristic, these standards are often insufficient for generative AI, where outputs are more nuanced and situation-specific. Therefore, carefully tailored evaluation criteria are essential, especially given the variability in AI performance across different healthcare settings, requiring reassessment when deployed in novel environments.

Beyond average performance metrics, it is vital to identify rare but serious errors that could adversely affect patients, moving safety analysis beyond typical summary statistics to understanding the frequency of potentially harmful recommendations. Such insights empower clinicians to maintain appropriate caution while using AI tools. Furthermore, essential performance and safety information should be transparently shared with end-users during training, through accessible "transparency notes" or "system cards," to foster calibrated trust and support ongoing feedback mechanisms that allow users to report concerns and contribute to system improvement.

In valuing clinician-AI interaction, performance evaluations should extend beyond standalone AI metrics to reflect the collaborative dynamic between healthcare providers and AI systems. Comparative assessments of clinician outcomes with and without AI assistance offer insight into the added value of these technologies. Developing advanced explanation features that clarify AI recommendations and their data sources can enhance user understanding and foster calibrated trust, forming a foundational element for future research and implementation strategies in healthcare AI.

f. CHI Views on Monitoring for Health AI Performance Drift

Managing performance degradation in AI-enabled medical devices presents a significant challenge due to factors like shifts in patient demographics, alterations in electronic health record (EHR) data formats, and updates to training data over time. These changes can reduce model accuracy even when the underlying algorithm remains unchanged. Effective real-world oversight requires continuous monitoring using interoperable data sources such as EHRs and patient-reported outcomes. Automated, validated monitoring tools, potentially leveraging AI themselves, should be complemented by expert human review to facilitate timely detection, root cause analysis, and corrective interventions.

Ongoing performance assessments should be supported by infrastructure capable of routine testing against representative clinical case sets. Any observed decline in performance must prompt thorough investigation and remedial actions, including model retraining or updates where needed. The Connected Health Initiative encourages adoption of machine learning operations

(MLOps) frameworks as foundational for sustainable, real-world surveillance and maintenance of healthcare AI models.

In the context of the Food & Drug Administration’s regulation of AI medical devices, CHI has emphasized that MLOps offer critical transparency into the behavior and evolution of AI systems over time and facilitate the implementation of Predetermined Change Control Plans (PCCPs) to ensure safe and compliant management of AI models within established boundaries. These practices enable continuous tracking of baseline real-world data, systematic monitoring of performance metrics, and automated evaluation processes that support ongoing oversight. This approach helps reduce regulatory complexities while safeguarding the safety and efficacy of AI technologies. Ensuring post-market surveillance is a collective duty shared among manufacturers, healthcare providers, industry groups, and standards organizations, with regulatory agencies playing a key role in setting standards and enforcing accountability.

g. Relying on International Standards

In establishing controls throughout the product lifecycle, CHI encourages Washington to harmonize its regulatory approach with internationally recognized standards, such as ISO 42001. This alignment aims to foster consistency and provide clear guidance that supports the safe and effective deployment of AI across all stages of product development and use. Additionally, the AITF final report should adopt industry-leading practices for communicating the intended use and enhancing transparency around AI products. By integrating these global standards and communication best practices, Washington State can facilitate greater clarity, trust, and uniformity in AI regulation.

**

CHI appreciates the opportunity to submit its comments to the AITF and urges its thoughtful consideration of the above/attached.

Sincerely,



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Appendices:

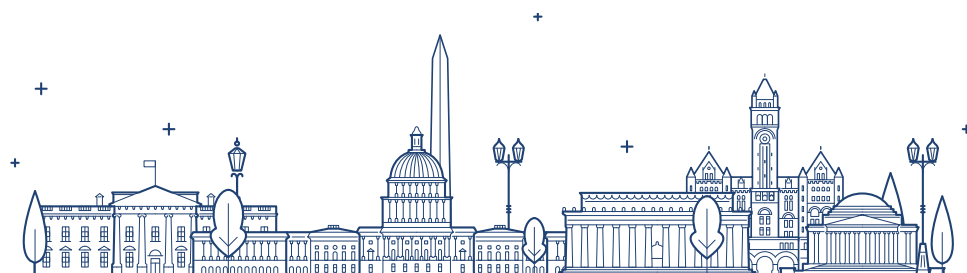
Appendix 1: CHI's Health AI Policy Principles

Appendix 2: CHI's Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem

Appendix 3: CHI's Health AI Roles & Interdependency Framework



Policy Principles for Artificial Intelligence in Health



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Policy Principles for AI in Health

Today, there are already many examples of AI systems, powered by streams of data and advanced algorithms, improving healthcare by preventing hospitalizations, reducing complications, decreasing administrative burdens, and improving patient engagement. AI systems offer the promise to rapidly accelerate and scale such results and drive a fundamental transformation of the current disease-based system to one that supports prevention and health maintenance. Nonetheless, AI in healthcare has the potential to raise a variety of unique considerations for U.S. policymakers.

Many organizations are taking steps to proactively address adoption and integration of AI into health care and how it should be approached by clinicians, technologists, patients and consumers, policymakers, and other stakeholders, such as the Partnership for AI, Xavier Health, the American Medical Association, and the Association for the Advancement of Medical Instrumentation and BSI. Building on these important efforts, the Connected Health Initiative's (CHI) Health AI Task Force is taking the next step to address the role of AI in healthcare.

First, AI systems deployed in healthcare must advance the “quadruple aim” by improving population health; improving patient health outcomes and satisfaction; increasing value by lowering overall costs; and improving clinician and healthcare team well-being. Second, AI systems should:

- Enhance access to health care.
- Empower patients and consumers to manage and optimize their health.
- Facilitate and strengthen the relationship and communication that individuals have with their health care team.
- Reduce administrative and cognitive burdens for patients and their health care team.

To guide policymakers, we recommend the following principles to guide action:

- **National Health AI Strategy:** Many of the policy issues raised below involve significant work and changes that will impact a range of stakeholders. The cultural, workforce training and education, data access, and technology-related changes will require strong guidance and coordination. Given the significant role of the government in the regulation, delivery, and payment of healthcare, as well as its role as steward of significant amounts of patient data, a federal healthcare AI strategy incorporating guidance on the issues below will be vital to achieving the promise that AI offers to patients and the healthcare sector. Other countries have begun to take similar steps (e.g., The UK's Initial Code of Conduct for Data Driven Care and Technology) and it is critical that U.S. policymakers collaborate with provider organizations, other civil society organizations, and private sector stakeholders to begin similar work.

- **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.
- **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 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 health care 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 health care are accessible and affordable. Significant resources may be required to scale systems in health care and policy-makers must take steps to remedy the uneven distribution of resources and access. There are varied applications of AI systems in health care 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 incentivize a pathway for the voluntary adoption and integration of AI systems into clinical practice as well as other applications under existing payment models.
- **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:
 - Ensuring 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 eased 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 bias inherent in all 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:
 - Require the identification, disclosure, and mitigation of bias while encouraging access to databases and promoting 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 health care 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.

Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem

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Executive Summary

Today, the most well-known FDA-approved applications of artificial intelligence and machine learning (AI/ML) technology in healthcare are diagnostic tools that help clinicians read and interpret images to predict, detect, and monitor a number of diseases, including diabetic retinopathy and lung cancer. In the future, the use of AI/ML technology in both operational and clinical settings promises to enable a more proactive approach to healthcare that promotes investments in preventative care that can result in fewer hospitalizations, fewer doctor visits, and fewer treatments. Across use cases, AI/ML technology is helping, and must increasingly help, the healthcare industry move away from a reactive disease treatment approach to a population health management approach that lowers costs and improves care.

The immense potential of AI/ML technology in healthcare may never be fully achieved, however, unless AI/ML technologies first earn the trust of healthcare professionals and patients. The cornerstone of building trust in AI/ML technologies is to enhance transparency – providing sufficient and appropriate information about the AI/ML, including its intended use, development, performance, and, when available, logic. The more understandable the decision-making process is for each individual technology, the more confidence there will be in AI/ML use in the healthcare system.

The recommendations in this Connected Health Initiative (CHI) AI Task Force report, informed by a public roundtable CHI held to address AI/ML transparency and extensive consultations with stakeholders from across the digital health ecosystem, represent a holistic approach to creating and maintaining the trust of both healthcare professionals and patients. The Task Force set out the foundational steps AI/ML tool developers must take to build transparency into their products, but it also outlines the important roles that clinicians, healthcare providers, regulators, academic medical institutions, and accrediting organizations must play.

The medical and technology communities have a shared responsibility to provide caregivers and patients (as well as other stakeholders) with an assurance of quality through truthful representations clearly indicating the AI/ML's intended uses and risks that would be reasonably understood by those intended and expected to use the AI/ML. Uptake will depend on the buy-in of clinicians who first develop trust in AI/ML software as a medical device (SaMD) through use and experience, establishing confidence as it is adopted into practice. Once adopted, clinicians can then work with their patients to explain their use of SaMD AI/ML and inspire the same trust and confidence from the patients in the output of the SaMD AI. Each step in this chain requires buy-in and support from policymakers (both within and outside of government).

The foundation of any successful use of AI/ML technologies in healthcare depends on the trust of healthcare professionals and patients, and we believe these recommendations present a clear path toward earning that trust.



About the Connected Health Initiative

CHI is the leading multistakeholder policy and legal advocacy effort driven by a consensus of stakeholders from across the connected health ecosystem. We aim to realize an environment where Americans can improve their health through policies that allow for connected health technologies to enhance health outcomes and reduce costs. Having members who are developers and users of connected health technologies across a wide range of use cases, CHI serves as an active advocate before Congress, numerous U.S. federal agencies, and state legislatures and agencies. We seek to advance responsible pro-digital health policies and laws in areas including reimbursement and payment, privacy and security, effectiveness, and quality assurance, U.S. Food and Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial intelligence and machine learning (AI/ML) in care delivery.

In 2019, CHI formed a Task Force focused on policy challenges and opportunities related to the use of AI/ML in healthcare. CHI's AI/ML Task Force already developed a set of health AI/ML policy principles addressing how policy frameworks should adopt the role of AI/ML in healthcare.¹ A cornerstone of these principles is the idea of requiring those developing, offering, or testing healthcare AI/ML systems to provide truthful representations clearly indicating the intended use and risks that would be reasonably understood by those intended and expected to use the AI/ML solution. Such steps will provide much-needed quality assurances to caregivers and patients (as well as other stakeholders) and assist in resolving data issues that arise when an algorithm is fed bad data that can skew its learning and introduce bias. CHI's AI Task Force later developed detailed Good Machine Learning Practices for FDA-regulated AI,² which reflect and elaborate on this priority. The recommendations in this paper build on those deliverables.

Numerous CHI Steering Committee members and other key stakeholders from throughout the healthcare value chain participate in this Task Force and share a commitment to realizing the value of AI/ML in healthcare while protecting patient safety and advancing the quadruple aim. The recommendations in this paper find basis in an evaluation by the Task Force of the healthcare ecosystem's implementation of AI/ML to date, challenges and opportunities reflected by federal policymakers, and the existing and emerging issues created by AI's deployment. This report is also informed by a CHI public roundtable held in April 2021 on how to improve AI/ML transparency for caregivers and patients based on their needs and concerns, during which a wide range of stakeholders contributed to a discussion exploring novel approaches to transparency of AI/ML taken today.

For more information, please visit www.connectedhi.com.

¹ <https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf>.

² <https://bit.ly/3B6nslm>.

Artificial Intelligence's Role in a Successful Healthcare Ecosystem Requires Transparency

Responsible implementation of AI/ML in healthcare leads to improved medical outcomes and overall increased cost savings

Today, there are many important operational and clinical AI/ML solutions in use and many more in development.³ Some of the most well-known applications of AI/ML in healthcare that have received market clearance from the FDA are diagnostic tools that help clinicians read and interpret images. For example, AI/ML image analysis software can assist clinicians in predicting, detecting, and monitoring a number of diseases, including diabetic retinopathy, lung cancer, prostate cancer, and skin cancer. Such AI/ML uses are generally intended to be used to assist human clinicians in providing more efficient and accurate results, rather than autonomously diagnosing disease.

Separately, research projects within and outside of clinical settings continue to further explore AI's potential to revolutionize healthcare. For example, an AI/ML system developed by researchers at Northwestern University's Feinberg School of Medicine correctly identifies small lung cancer tumors nearly 95 percent of the time, while radiologists undertaking the same task unassisted are correct only 65 percent of the time.⁴ Researchers at Carnegie Mellon developed a miniature mobile robot called HeartLander that uses machine learning algorithms to make treating ventricular fibrillation (VF)—a deadly type of cardiac arrhythmia that requires cardioversion and then, if the patient survives, surgical removal of faulty heart tissue—far safer and less invasive.⁵

As a recent research paper discussing challenges related to deployment of AI/ML technologies into the clinical setting stated, “the success of a deep learning model does not rest solely on its accuracy.”⁶ The researchers noted that clinician “experiences with the system, and the socio-environmental factors that impacted system performance” must be evaluated and addressed for these systems to function in the clinical setting with the accuracy rates illustrated in the lab setting.⁷ Clearly, if the challenges of integrating AI/ML tools into clinical workflow can be overcome, AI/ML can support clinicians in a wide range of other areas. Its potential to reshape the healthcare landscape is profound, especially in the improvements it can bring to any process within healthcare operation and delivery.

Medical devices and systems that use AI/ML also represent a real opportunity to drive down healthcare costs for consumers, practitioners, and healthcare businesses alike. It is estimated that AI/ML applications can cut annual U.S. healthcare costs by \$150 billion by 2026.⁸ Most of these cost reductions stem from changing the healthcare model from a reactive to a proactive approach, focusing on health management rather than disease treatment. This focus on using AI/ML as an investment in

3 The FDA now publicly lists AI/ML medical devices cleared for marketing in United States, and includes their intended uses. See <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>.

4 <https://www.nature.com/articles/d41586-020-03157-9>

5 <https://onlinelibrary.wiley.com/doi/10.1002/rcs.2297>

6 Emma Beede et al, A Human-Centered Evaluation of a Deep Learning System Deployed in Clinics for the Detection of Diabetic Retinopathy, CHI Conference on Human Factors in Computing Systems (April 2020) available at <https://dl.acm.org/doi/fullHtml/10.1145/3313831.3376718>.

7 *Id.*

8 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7325854/>.

preventative care can result in fewer hospitalizations, fewer doctor visits, fewer treatments, and thus fewer side effects. AI-based technology will have an important role in helping people stay healthy via remote monitoring technologies and coaching and will ensure earlier diagnosis, tailored treatments, and more efficient follow-ups.⁹

For example, AI/ML image analysis technologies can reduce medical expenses in several ways. For one, AI/ML systems can be very helpful in augmenting a clinician's analysis and treatment decisions more quickly. AI/ML technologies enable clinicians to provide the same, accurate service in a fraction of the time, increasing the volume of patients without increasing time spent treating them.¹⁰ Second, a patient whose disease is diagnosed early will pay less to treat or cure the disease than one who catches it later. The longer a disease goes undiagnosed, the more damage it causes and more resources it takes to treat, assuming it remains treatable at all. Wearable technologies that use AI, such as remote monitoring technologies, increase access to healthcare and increase engagement in treatment plans by, for example, analyzing user health data in real time and notifying wearers or their healthcare providers (or both) of potential health issues.

By introducing new, accurate, and timely data streams for human clinicians' review, AI/ML medical tools and systems that use wearable technologies can enable practitioners to come up with care and treatment options without having to see a patient in person as much, reducing administrative and in-office visit resource expenditures, and, during outbreaks of communicable diseases, at lower risk of infection to both provider and patient. The use of such technologies will also enhance patient engagement in their own care plans. This same concept also applies to laboratory technologies that use AI/ML systems, where the work hours currently required for repetitive and routine tasks could see drastic reductions, significantly cutting labor costs.¹¹

Increased efficiency, precision, and affordability are just some of the benefits that AI/ML can offer the healthcare community and those they serve, but realizing these benefits will depend on the buy-in of the provider and patient communities as well as support for responsible deployments from policymakers. CHI's AI/ML Task Force released detailed policy principles,¹² as well as proposed good machine learning practices for AI/ML meeting the definition of a medical device,¹³ to address these challenges. Notably, CHI's AI/ML Task Force has acknowledged that without its processes being understandable by humans and transparency (providing sufficient and appropriate information about the AI/ML, including its intended use, development, performance, and, when available, logic), particularly for patients and caregivers, AI/ML cannot most effectively improve healthcare. Namely, those developing, offering, or testing healthcare AI/ML systems must provide truthful and understandable representations regarding intended use and risks that would be reasonably understood by those intended, as well as expected, to use the AI/ML software as a medical device (SaMD) solution.

9 *Id.*

10 See McPhail et al, Stage at diagnosis and early mortality from cancer in England (Br J Cancer 2015), [doi: 10.1038/bjc.2015.49](https://doi.org/10.1038/bjc.2015.49).

11 Rong, et al, "Artificial Intelligence in Healthcare: Review and Prediction Case Studies," Engineering, [doi: 10.1016/j.eng.2019.08.015](https://doi.org/10.1016/j.eng.2019.08.015) at Sec. 2.2.

12 <https://actonline.org/wp-content/uploads/Policy-Principles-for-AI.pdf>.

13 <https://bit.ly/3B6nslm>.

How Can Transparency into Healthcare AI/ML Solutions be Advanced?

While evidence of healthcare AI's potential for widespread benefit continues to build, that potential can never be realized without healthcare professionals and patients understanding and trusting AI/ML solutions. The more transparent the decision-making process is for each individual technology, the more confidence there will be in AI/ML use in the healthcare system.¹⁴ Transparency for healthcare AI's intended uses must happen at several levels, disseminating tailored messaging to specific audiences that require insights into the AI/ML solution to make informed decisions. Building the trust that must be a foundation for the responsible deployment of AI/ML is a shared responsibility amongst developers, providers, and regulators.

Providing transparency into health AI/ML must start with the developers of the AI/ML tools. Then, uptake of AI/ML will need to be built on the buy-in of clinicians who first develop trust in AI/ML SaMD through use and experience, establishing confidence as it is adopted into practice. Once adopted, the provider can then work with his or her patients to explain their use of SaMD AI/ML and inspire the same trust and confidence by the patient in the output of the SaMD AI. Each step in this chain requires buy-in and support from policymakers (both within and outside of government).

The CHI AI/ML Task Force's recommendations for enhancing transparency for health AI/ML include:

Developers of AI/ML SaMD should:

- Prioritize making healthcare AI/ML solutions reasonably safe, efficacious, and equitable from the earliest stages of design, considering the perspectives of both patients and providers, leveraging and where necessary tweaking medical AI/ML guidelines on research and ethics,¹⁵ leading standards,¹⁶ and other resources as appropriate.
- Employ algorithms that produce repeatable results and, when feasible, are auditable, and make decisions that, when applied to medical care (such as screening, diagnosis, or treatment), are clinically validated and where possible understandable using rigorous procedures with documented methods and results, fostering efficacy through continuous monitoring.
- Rigorously identify, disclose, and mitigate biases in datasets used to train algorithms.
- Utilize risk-scaled privacy protection mechanisms for patients' data to account for the fact that the analysis by health AI/ML tools provides greater potential utility of those data items to other individuals, entities, and machines, providing many new uses for, and ways to analyze, the collected data, as well as correspondingly stronger incentives for malefactors to attempt to obtain access unlawfully. Specific uses of data that require additional safeguards (such as genomic

¹⁴ <https://www.bsigroup.com/globalassets/localfiles/en-gb/about-bsi/nsb/innovation/mhra-ai-paper-2019.pdf>

¹⁵ E.g., World Health Organization, 'Ethics & Governance of Artificial Intelligence for Health' (2021), available at <https://www.who.int/publications/i/item/9789240029200>.

¹⁶ E.g., Consumer Technology Association, 'The Use of Artificial Intelligence in Health Care: Trustworthiness (ANSI/CTA-2090)' (2021), available at <https://shop.cta.tech/collections/standards/products/the-use-of-artificial-intelligence-in-healthcare-trustworthiness-cta-2090>.

information) may necessitate a tailored approach or enhanced protections from discrimination (e.g., pre-existing conditions or genomic information may be needed for patients).

- Comply with all applicable legal and regulatory requirements.
- Develop a tailored communications and engagement plan that gives patients and providers representative of the AI/ML tool's user group a reasonably justifiable level of confidence in healthcare AI's efficacy. Such communications should enable these patients and providers to visualize the AI, and to receive direct and clear information about how their health data are being collected and used (while also avoiding information overload) and how biases in data that exacerbate disparities in healthcare are being mitigated. Reflecting that the division of labor between the developers of AI-enabled tools and the clinician or patient is critical, clearly explain intended uses, including whether a tool might include the restriction that it is not for diagnostic use or for informational purposes only, as well as risks.

Providers should:

- Develop their own risk-based and tailored communications and engagement plan that enables them to explain to patients the development of the AI/ML application, its maintainance, its performance, and how it aligns with the latest best practices and regulatory requirements to improve patient safety using easily understood and standardized formats. Providers should also acknowledge that “best practices” are dynamic and prone to obsolescence.
- Offer further detail for patients in additional resources that explain the clinical testing of AI/ML applications and the confirmation of the results by clinical experts.

The Food and Drug Administration (FDA) should:

- Leverage its successful approach to authorizing medical device AI¹⁷ that has already safely brought health AI/ML innovations to patients and providers to develop a comprehensive regulatory approach to AI/ML that meets the definition of a medical device. The FDA can accomplish this by, for example, progressing its Software Precertification Pilot¹⁸ to a full program available to all developers of SaMD AI, FDA can also update its rules and processes to realize its envisioned total product lifecycle (TPLC) regulatory approach, facilitating a potentially rapid cycle of product improvement and allowing these devices to continually improve while providing effective safeguards. This new approach should leverage CHI's Good Machine Learning Practices to address both locked and continuously learning AI.
- Evolve its requirements on reporting type and frequency so that such requirements can be adapted and scaled based on relevant factors such as risk, extent, and magnitude of

17 Software as a Medical Device (SaMD): Clinical Evaluation:

<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm524904.pdf>; Deciding When to Submit a 510(k) for a Software Change to an Existing Device: <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514737.pdf>.

18 Pre-Cert Program Version 1.0 Working Model:

<https://www.fda.gov/downloads/MedicalDevices/DigitalHealth/DigitalHealthPreCertProgram/UCM629276.pdf>.

modifications, and the demonstrated reliability of the AI (e.g., quality control plans for updates).¹⁹ Initially, the FDA should finalize guidance on SaMD pre-specifications and algorithm change protocol inputs that FDA should periodically receive.

- Develop methods to efficiently communicate when FDA has authorized a product developed with or that utilizes AI/ML, along with information on how it was developed, is maintained and performs, and aligns with the latest best practices and regulatory requirements that ensure patient safety using easily understood (e.g., infographics) and standardized formats. For example, where approval is required for the deployment of new solutions in the market, the FDA should provide information describing the datasets used to train the AI/ML software and what efforts are being taken to align with ethical standards and to mitigate data biases. This work should build on the recently released database of AI-enabled devices legally marketed in the United States from the FDA's Digital Health Center of Excellence.²⁰
- Serve as a coordinator and convenor of other U.S. federal agencies to ensure a harmonized approach to health AI/ML transparency across government.
- Build on its leadership to date within the International Medical Device Regulatory Forum (IMDRF), promote its approach to SaMD AI/ML to improve approaches to transparency internationally.
- Host recurring public events, in partnership with health AI/ML developers, patients, and providers, that feature the FDA Digital Health Center of Excellence's latest approaches and thinking, as well as demonstrations of AI/ML in healthcare today.

The Centers for Medicare and Medicaid Services (CMS) should:

- Continue to develop its understanding of medical AI/ML definitions, present-day and future AI/ML solutions, how AI/ML is changing the practice of medicine, and the future of AI/ML medical coding.
- Develop Medicare support mechanisms for the use of AI/ML by providers based on clinical validation, alignment with clinical decision-making processes familiar to providers, and high-quality clinical evidence.
- Build on support provided in the Medicare system for the use of health AI,²¹ develop easy to understand resources for Medicare beneficiaries that capture how AI/ML is being used in the Medicare system and what it means to patients. CMS should leverage its Advisory Panel on Outreach and Education²² to develop this messaging.

19 As the FDA has noted, new reporting mechanisms for a scalable AI/ML medical device reporting structure “may require additional statutory authority to implement fully”. Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback (Apr. 10, 2021) at 15. Available at <https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf>.

20 <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>. This FDA list currently provides key information such as submission number, device and company name, and date of marketing authorization of the device (510(k) clearance, granting of De Novo, or PMA approval).

21 For example, CMS already provides payment for CPT code 92229 (point-of-care diabetic retinopathy automated analysis and provides a diagnostic report using AI).

22 <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APOE>.

The Federal Trade Commission (FTC) should:

- Support ways to mitigate biases or other unfair outcomes from healthcare AI,²³ and, where appropriate, enforce against violations of key laws such as Section 5 of the FTC Act, which prohibits unfair or deceptive practices, where appropriate.

Accrediting and Licensing Bodies, and Medical Specialty Societies and Boards should:

- Develop medical standard of care and ethical guidelines to address emerging issues with the use of SaMD AI/ML in healthcare needed to advance the quadruple aim.
- Develop and disseminate guidance and education on the responsible deployment of SaMD AI, both generally and for specialty-specific uses.

Academic and Medical Education Institutions should:

- Develop and include curriculum that will advance understanding of and ability to use healthcare AI/ML solutions, which should be assisted by inclusion of non-clinicians, such as data scientists and engineers, as instructors. Ongoing training and continuing education should also advance understanding of the safe and effective use of AI/ML in healthcare delivery, addressing both its capabilities and limitations.
- Develop curriculum to advance understanding of data science research to help inform ethical bodies such as Institutional Review Boards (IRBs) that are reviewing protocols of clinical trials of AI-enabled medical devices.

²³ <https://www.ftc.gov/news-events/blogs/business-blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai>

Conclusion

CHI is pleased to present its recommendations on AI/ML transparency for the consideration of the healthcare ecosystem, policymakers, and others. We are committed to continued engagement with the digital health community writ large to realize the both the responsible deployment of AI/ML across healthcare and its immensely positive societal benefit.

CHI Health AI Roles & Interdependency Framework

Connected**Health**Initiative



Overview

Artificial Intelligence (AI), especially generative AI, is already a powerful tool in healthcare, offering amazing potential to upgrade patient care by improving care outcomes and patient experiences, reducing healthcare provider burnout by simplifying administrative tasks, and helping to lower the total cost of care. One of the most helpful ways to see the value of AI in healthcare is to view the question through the lens of the “quadruple aim” framework. Built on the Institute for Healthcare Improvement’s “triple aim,” a widely accepted compass to optimize health system performance, the quadruple aim focuses on four key areas where health systems need to be improved, all of which AI is already, and will continue to, provide value across:

- Enhancing population health.
- Improving patient experience, satisfaction, and health outcomes.
- Augmenting clinician and healthcare team experience and satisfaction.
- Lowering overall costs of healthcare.

CHI has explored the ways in which AI is supporting each of the four aims of the quadruple aim in CHI’s paper, [Why Does Healthcare Need AI?](#)

But this promising technology is not infallible, and as healthcare organizations seek opportunities to use AI, stakeholders are facing important questions about how various risks or limitations should be handled in the development, distribution, deployment, and end use chain. Many organizations involved in the creation or application of healthcare AI have started to develop Responsible AI programs aimed at managing these risks or limitations within their organization. But as we have learned from other new technologies in the past, stakeholders can benefit from a clear discussion around all the safety measures and other actions that are needed, and how those actions might be applied at different steps from creation to the operation of the tool by the end user. This discussion will help various stakeholders better determine accountability for responsible AI best practices across this chain of stakeholders.



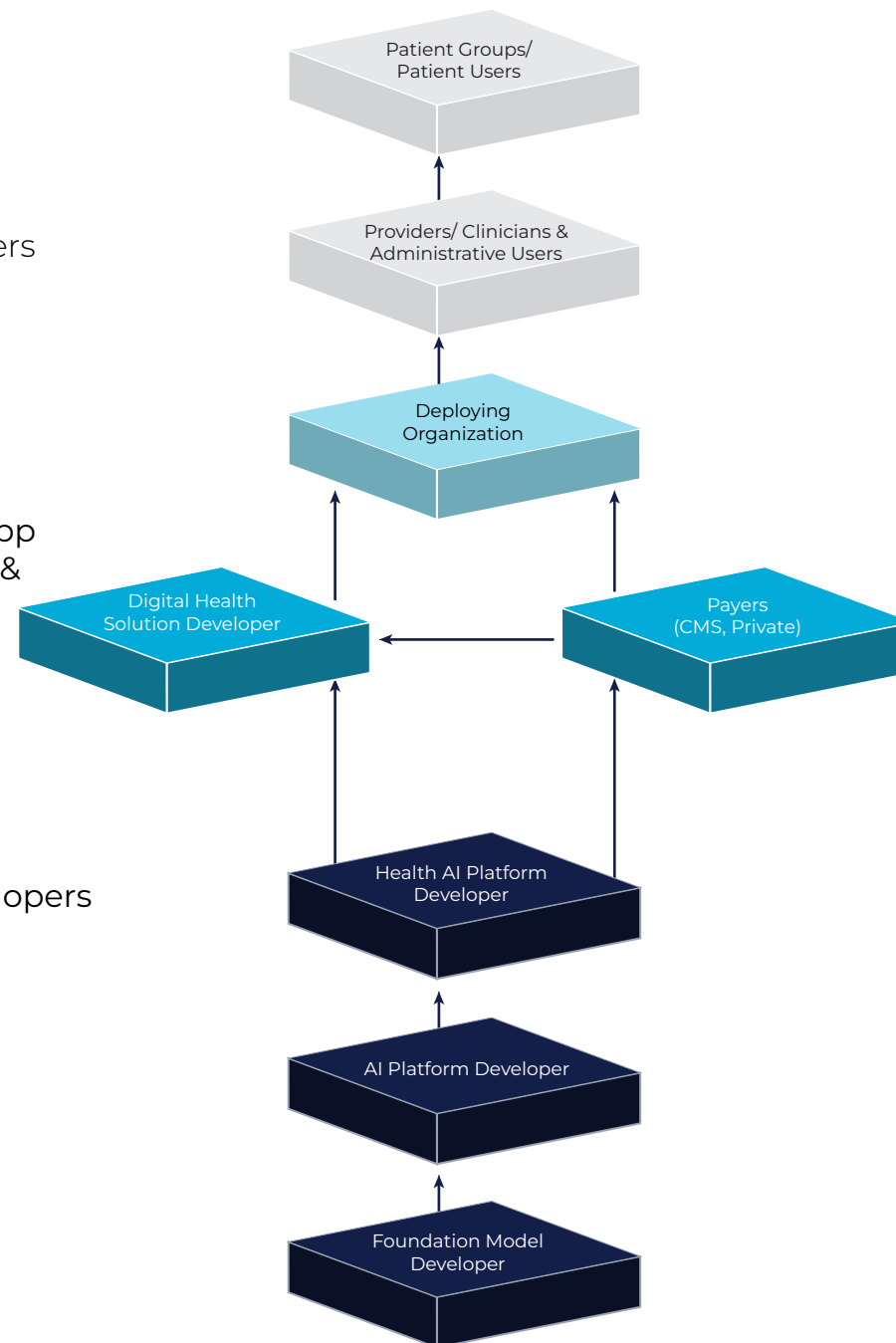
CHI urges all stakeholders in the healthcare ecosystem that are developing and using AI to align with **CHI's consensus health AI principles**, which recognize the shared responsibility for AI safety, efficacy, and transparency. CHI supports (1) leveraging a risk-based approach to AI harm mitigation where the level of review, assurance, and oversight is proportionate to potential harms and (2) those in the value chain with the ability to minimize risks based on their knowledge and ability, and having appropriate responsibilities and incentives to do so.

Further, managing AI/Machine Learning (ML) risks will be more challenging for small to medium-sized organizations, depending on their capabilities and resources. Building on these general health AI principles, CHI proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use. Then, CHI suggests roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept. These roles and interdependencies are also mapped to the Functions defined in the National Institute of Standards and Technology's (NIST's) AI Risk Management Framework (RMF).

1
Solution Users

2
Solutions/App
Developers &
Deployers

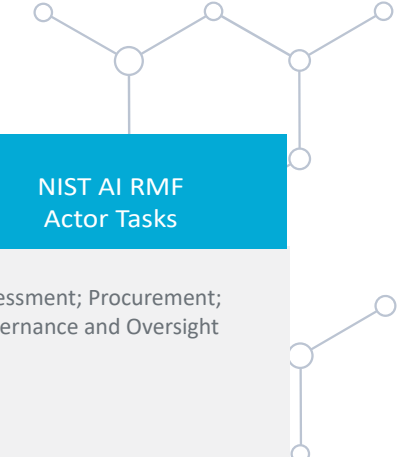
3
AI/ML Developers



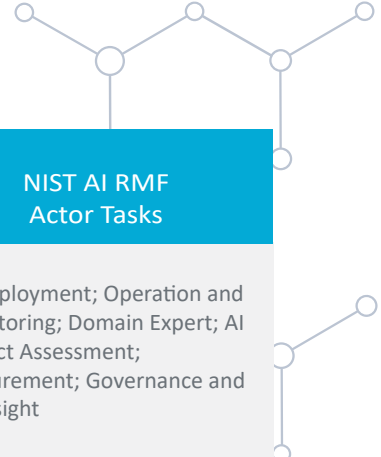
Note: Depending on the use case, some of the roles in the healthcare AI/ML value chain may be occupied by the same party; in other scenarios, some roles may not be occupied.

Stakeholder Group	Definition	Roles	NIST AI RMF Actor Tasks
AI/ML Developers	Someone who designs, codes, researches, or produces an AI/ML system or platform for internal use or for use by a third party. See below for defined Subgroups of this Stakeholder Group along with recommendations specific to that Subgroup.	- Informing deployers and users of data requirements/definitions, intended use cases/populations and applications (e.g., disclosing sufficient detail allowing providers to determine when an AI-enabled tool should reasonably apply to the individual they are treating), including whether the AI/ML tools are intended to augment human work versus automate workflows, and status of/compliance with all applicable legal and regulatory requirements. - Prioritizing safety, efficaciousness, transparency, and data privacy and security from the earliest stages of design, leveraging (and, where appropriate updating) existing medical AI/ML guidelines on research and ethics, leading standards, and other resources as appropriate. - Employing algorithms that produce repeatable results and, when feasible, are auditable, and make decisions that (when applied to medical care) are clinically validated, fostering efficacy through continuous monitoring. - Utilizing risk management approaches that scale to the potential likely harms posed in intended use scenarios to support safety, protect privacy and security, avoid harmful outcomes due to bias, etc. - Providing information that enables those further down the value chain can assess the quality, performance, and utility of AI/ML tools. - Aligning with relevant ethical obligations and international conventions on human rights and supporting the development of new ethical guidelines to address emerging issues as needed.	AI Deployment; Operation and Monitoring; Test, Evaluation, Verification, and Validation (TEVV); Human Factors; Domain Expert; AI Impact Assessment; Governance and Oversight

Stakeholder SubGroup	Definition	Roles
Foundation Model Developer	Someone who creates or modifies large and generalizable machine learning models that can be used/adapted for various downstream tasks and applications, such as natural language processing, computer vision, or software development.	Building on the cross-AI/ML Developer roles noted above: - Assessing what bias and safety issues might be present in its Foundation Model, and documenting steps taken to mitigate those issues in its Transparency Documentation (e.g., Transparency Notes, System Cards and product documentation). - Providing clear guidance on (1) how to use and adapt its Foundation Model for various foreseeable downstream tasks and applications, and (2) what limitations or risks may arise from doing so based on challenges discovered during testing and deployment.
AI Platform Developer	Someone who leverages existing foundation models and builds an industry-agnostic platform that enables other developers to access, customize, and deploy these models for various use cases and applications, such as natural language processing, computer vision, and/or software development.	Building on the cross-AI/ML Developer roles noted above: Testing for, identifying, and mitigating bias and safety issues that may arise from using or modifying existing foundation models for its AI Platform, and documenting these issues and steps taken to address them in its transparency documentation (e.g., transparency notes, system cards and product documentation).
Health AI Platform Developer	Someone who creates or uses AI-powered platforms that are tailored for the healthcare domain, such as administrative efficiency, diagnostics, therapeutics, or research. These platforms may leverage foundation models (or other types of machine learning models or solutions), such as AI platforms, that are suitable for specific healthcare problems and data sources.	Building on the cross-AI/ML Developer roles noted above: - Meeting specific requirements and standards of the healthcare domain, such as accuracy, efficacy, explainability, and compliance with regulations. - Testing for, identifying, and mitigating any bias and safety issues that may affect the health outcomes of patients or the performance of clinicians using the Health AI Platform, and documenting these issues and the steps it has taken to address them in its transparency documentation (e.g., transparency notes, system cards and product documentation).
Digital Health Solution Developer	Someone who creates complete digital tools and technologies to improve health and healthcare outcomes, such as providing diagnostic and administrative solutions for clinicians, patients, and healthcare organizations. They may build digital health solutions with both health AI platforms, which are specialized for the health care domain, and AI platforms, which are more general and adaptable for various use cases and applications.	Building on the cross-AI/ML Developer roles noted above: - Specifying appropriate uses for its digital health solution to avoid amplifying bias or safety issues that may exist in the underlying foundation models, AI platforms, or health AI platforms. - Designing user interfaces to enable an end user to safely and effectively act upon the output of the tool, such as providing explanations, feedback mechanisms, or human oversight options, providing clear documentation to Deploying Organizations and Users to help them avoid bias and safety issues.



Stakeholder Group	Definition	Roles	NIST AI RMF Actor Tasks
Deploying Organization (Healthcare Provider or Payor)	Someone who is a healthcare providers and health care payors that and is deploying solutions built by Digital Health Solution Developers. They may also have their own internal IT staff that use health AI platforms or general AI platforms to develop their own custom digital health solutions.	Respecting that managing AI/ML risks will be more challenging for small to medium-sized organizations depending on their capabilities and resources: - Adopting AI/ML Developer instructions for use, specifying appropriate uses for Users through governance policies to avoid bias and safety issues that may exist in the underlying foundation models, AI platforms, or health AI platforms. - Developing and leveraging digital health solutions that augment efficiencies in coverage and payment automation, facilitate administrative simplification/reduce workflow burdens, and are fit for purpose. - Setting organization policy/designing workflows to reduce the likelihood that a User will act upon the output of the tool in a way that would cause fairness/bias or safety issues (tailored explanations, feedback mechanisms, and/or human oversight options). - Developing and organizational guidance on how the digital health solution should and should not be used. - Creating risk-based, tailored communications and engagement plans to enable easily understood explains to patients about how the digital health solution was developed, its performance and maintenance, and how it aligns with the latest best practices and regulatory requirements.	Assessment; Procurement; Governance and Oversight
Provider/Clinician Users and Administrative Users	Someone who directly interacts with or benefits from the digital health solutions that are built by Digital Health Solution Developers or by the internal IT staff of the Deploying Organization. They may include clinicians, such as doctors, nurses, or pharmacists, and administrative staff, such as billing, claims, or customer service personnel, in the provider and payor organizations.	Respecting that managing AI/ML risks will be more challenging for small to medium-sized organizations depending on their capabilities and resources: - Taking required training and incorporating employer guidance about use of AI/ML digital health solutions. - Documenting (through automated processes or otherwise) whether AI is being used in medical records and report any issues or feedback to the developer, such as errors, vulnerabilities, biases, or harms (where AI/ML's use is known by the User). - Ensuring there is appropriate clinician review and review of the output or recommendations from each digital health solution prior to acting on it (where AI/ML's use is known by the User).	AI Deployment; Operation and Monitoring; Domain Expert; AI Impact Assessment; Procurement; Governance and Oversight



Stakeholder Group	Definition	Roles	NIST AI RMF Actor Tasks
Payer Users (Centers for Medicare and Medicaid Services [CMS], State Medicaid, Private)	Someone that pays for the cost of healthcare services administered by a healthcare provider.	- Leveraging AI/ML systems that improve efficiencies in coverage and payment automation, facilitate administrative simplification, and reduce provider workflow burdens. - Aligning with medical AI/ML definitions, present-day and future AI/ML solutions, the future of AI/ML medical coding changes and trends. - Developing support mechanisms for the use of AI/ML by providers based on clinical validation, aligning with clinical decision-making processes familiar to providers, and high-quality clinical evidence. - Assuring that AI/ML systems allow for the individualized assessment of specific medical and social circumstances and provider flexibility to override automated decisions, ensuring that use of AI/ML does not improperly reduce or withhold care, or overrides the provider's clinical judgement. - Disclosing information about training and reference data to demonstrate that AI/ML systems do not create or exacerbate inequities and that protections are in place to mitigate bias. - Developing and proliferating easy to understand resources for beneficiaries and their providers that capture how and when AI/ML is being used, what information it is leveraging, and what it means to patients.	AI Deployment; Operation and Monitoring; Domain Expert; AI Impact Assessment; Procurement; Governance and Oversight
Patient Groups/ Patient Users	Someone who uses digital tools and technologies that are built by Digital Health Solution Developers or experiences their use in treatment.	- Developing and proliferating easy to understand resources that capture how AI/ML is being used and what it means to patients/patient groups, including explanations on the purpose and limitations of the digital health solutions that they use or benefit from (e.g., diagnostic, therapeutic, administrative). - Raising awareness of patients' rights and choices when using digital health solutions, such as consent, access, correction, or deletion of their personal data.	Human Factors
Standard-Setting Organizations	An organization whose primary function is developing, coordinating, promulgating, revising, amending, reissuing, interpreting, or otherwise contributing to the usefulness of technical standards to those who employ them.	Developing and promoting adoption of international voluntary/non-regulatory consensus standardized approaches and resources to steward a shared responsibility approach to AI.	Human Factors; Domain Expert; AI Impact Assessment; Governance and Oversight

Stakeholder Group	Definition	Roles	NIST AI RMF Activities
Certification Bodies & Test Beds	A certification body is a third-party organization that assures the conformity of a product, process or service to specified requirements. A test bed is a platform for conducting rigorous, transparent, and replicable testing of scientific theories, computing tools, and new technologies to a standard.	- Creating and making available transparent and reliable processes for the assurance of conformity to voluntary AI standards. - Creating and making available voluntary sandbox environments to help evaluate the usability and performance of AI/ML-based high-performance computing applications to advance the understanding of how reliable and efficacious AI, and to provide an appropriate assurance of reliability and efficacy.	Test, Evaluation, Verification, and Validation (TEVV); Human Factors; Domain Expert; AI Impact Assessment; Governance and Oversight
Accrediting and Licensing Bodies, and Medical Specialty Societies and Boards	Accrediting and licensing bodies are governing authorities that establish the suitability of any participating certification body. Notably, state-level board serve this purpose for physicians, nurses, and other clinicians to standards set by each state. Medical specialty societies are organizations for physicians, research and clinical scientists who are actively involved in the study of a particular specialty.	- Based on clinical needs and expertise, developing and setting the medical standard of care and ethical guidelines to address emerging issues with the use of AI/ML in healthcare needed to advance the quadruple aim. - Identifying the most appropriate uses of AI-enabled technologies and developing and disseminating guidance and education on the responsible deployment of AI/ML in healthcare, both generally and for specialty-specific uses.	Test, Evaluation, Verification, and Validation (TEVV); Human Factors; Domain Expert; AI Impact Assessment; Governance and Oversight
Academic and Medical Education Institutions	Tertiary educational institutions, professional schools, or forms a part of such institutions, that teach medicine and awards a professional degree for physicians or other clinicians.	- Developing and teaching curriculum that will advance understanding of and ability to use healthcare AI/ML solutions responsibly, which should be assisted by inclusion of non-clinicians such as data scientists and engineers as instructors. - Developing curriculum to advance the understanding of data science research to help inform ethical bodies (e.g., Institutional Review Boards that are reviewing protocols of clinical trials of AI/ML-enabled medical devices).	Human Factors; Domain Expert; AI Impact Assessment