ConnectedHealthInitiative

March 10, 2024

Katie L. Templeton, JD
Chair
Ethics and Professionalism Committee
Federation of State Medical Boards
1775 I St NW (Suite 410)
Washington, DC 20006

Dear Ms. Templeton:

The Connected Health Initiative (CHI) appreciates the opportunity to submit views to the Federation of State Medical Boards (FSMB) on its draft policy for the use of artificial intelligence (AI) in medicine.[1]

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. We agree with FSMB medical AI holds tremendous potential to aid healthcare providers in diagnosis, treatment selection, clinical documentation, and other tasks to improve quality, access, and efficiency; but that AI technologies also introduce risks if deployed without proper guardrails and understanding. We support FSMB's efforts to take a proactive governance approach anchored in ethical principles to ensure that state medical boards promote safe and effective integration of AI, in its various forms, while prioritizing patient wellbeing.

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. Building on these important efforts, CHI's Health AI Task Force has taken a critical further step in

[1] https://www.fsmb.org/siteassets/communications/report-ethics-and-professionalism-draft-for-comment.pdf.

developing cross-stakeholder consensus principles for the creation, deployment, and maintenance of AI across healthcare settings in its *Policy Principles for Artificial Intelligence in Health*,[2] along with the following, which we urge FSMB to align with in its policies for health AI:

- CHI's *Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem*:[3] https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf
- CHI's *Health AI Roles and Interdependencies Framework*:[4] https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf

We also encourage FSMB to align its approach to AI in medecine with the following:

- NIST's AI Risk Management Framework: https://www.nist.gov/itl/ai-risk-management-framework
- ISO/IEC 23894:2023 (Information technology, Artificial intelligence, Guidance on risk management): https://www.iso.org/standard/77304.html

Specific to FSMB's draft report, we also offer the following input specific to topics raised:

Ethical Use of AI: 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. FSMB, and state medical boards, should ensure that their frameworks:

- 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.

[2] Available at https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf, and also included as **Appendix A**.

[3] Also included as **Appendix B**.

[4] Also included as **Appendix C**.

- 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.

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.

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

Accountability: 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 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 has developed its *Health AI Roles and Interdependencies Framework*[5] which 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. Specifically, we offer the following recommendations for Deploying Organizations and, separately, Provider/Clinician Users and Administrative Users:

Deploying Organization (Healthcare Provider or Payor) – respecting that managing AI/ML risks will be more challenging for small to medium-sized organizations depending on their capabilities and resources, the following roles are suggested:

- 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.

Provider/Clinician Users and Administrative Users – respecting that managing AI/ML risks will be more challenging for small to medium-sized organizations depending on their capabilities and resources, the following roles are suggested:

- Taking required training and incorporating employer guidance about use of AI/ML digital health solutions.

[5] Available at https://connectedhi.com/wp-content/uploads/2024/02/CHI-Health-AI-Roles.pdf and also included with these comments as **Appendix C**.

- 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).

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CHI appreciates FSMB's consideration of the above views. We urge FSMB to contact the undersigned with any questions or ways that we can assist moving forward.

Sincerely,

Brian Scarpelli
Executive Director

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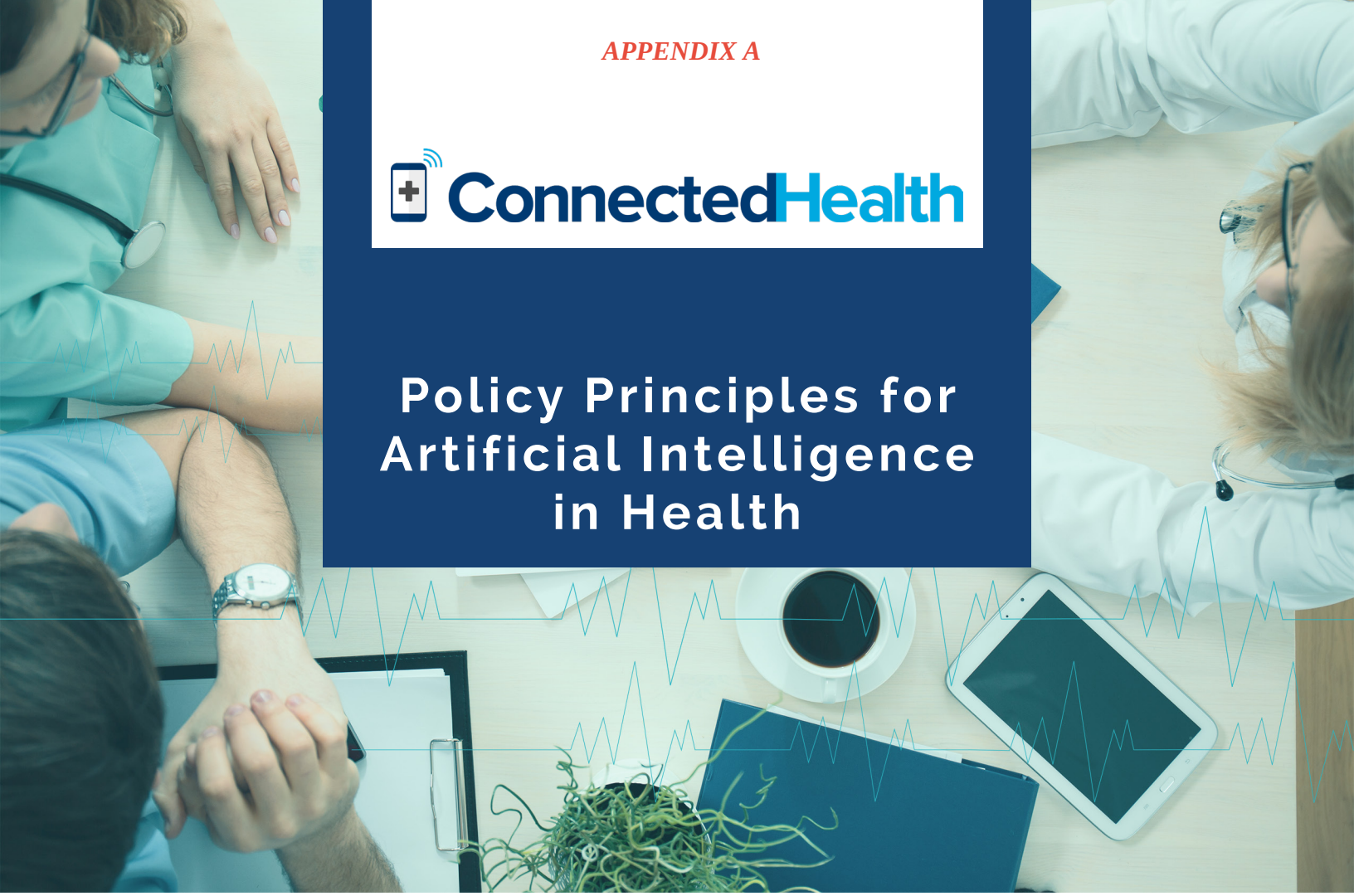
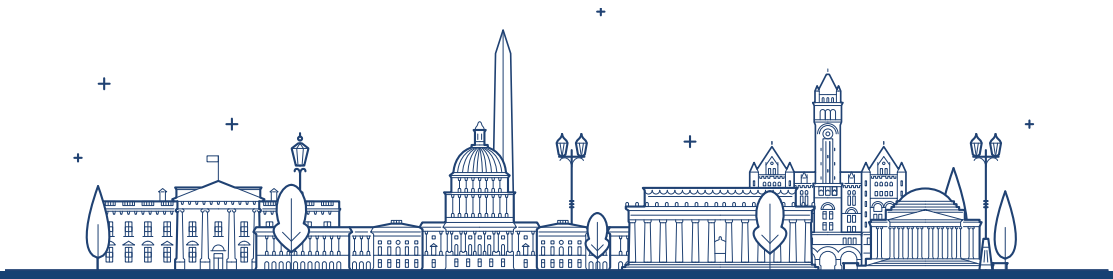
APPENDIX A

ConnectedHealth

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.

APPENDIX B

ConnectedHealth

Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem

OCTOBER 2021

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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 acheived, 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 evaulated 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.
11 Rong, et al, "Artificial Intelligence in Healthcare: Review and Prediction Case Studies," Engineering, doi: 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 maintainnace, 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 AI[17] 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 Pilot[18] 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 Education[22] 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.

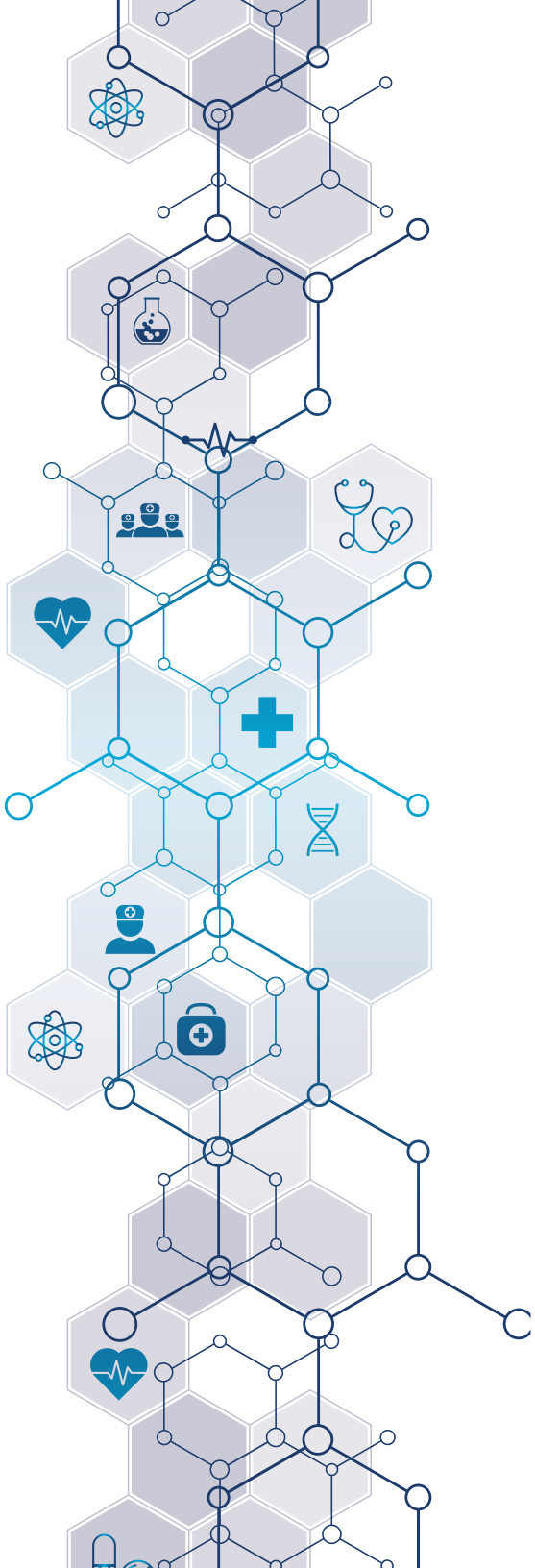
23 https://www.ftc.gov/news-events/blogs/business-blog/2021/04/aiming-truth-fairness-equity-your-companys-use-ai

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.

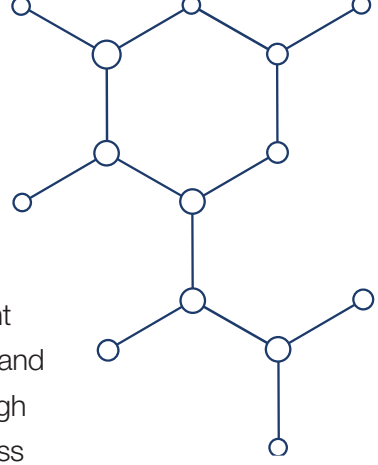
APPENDIX C

CHI Health AI Roles & Interdependency Framework



ConnectedHealthInitiative

Overview

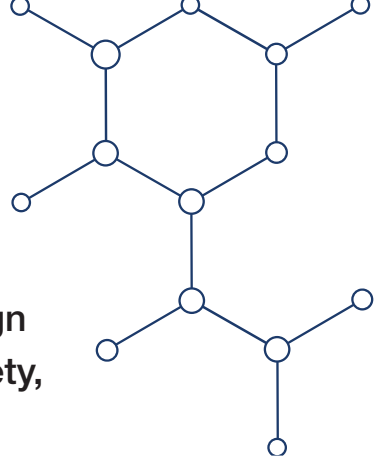


Artificial Intelligence (AI), especially generative AI, is already a powerful tool in healthcare, offering amazing potential to upgrade patient care by improving care outcomes and patient experiences, reducing healthcare provider burnout by simplifying administrative tasks, and helping to lower the total 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.



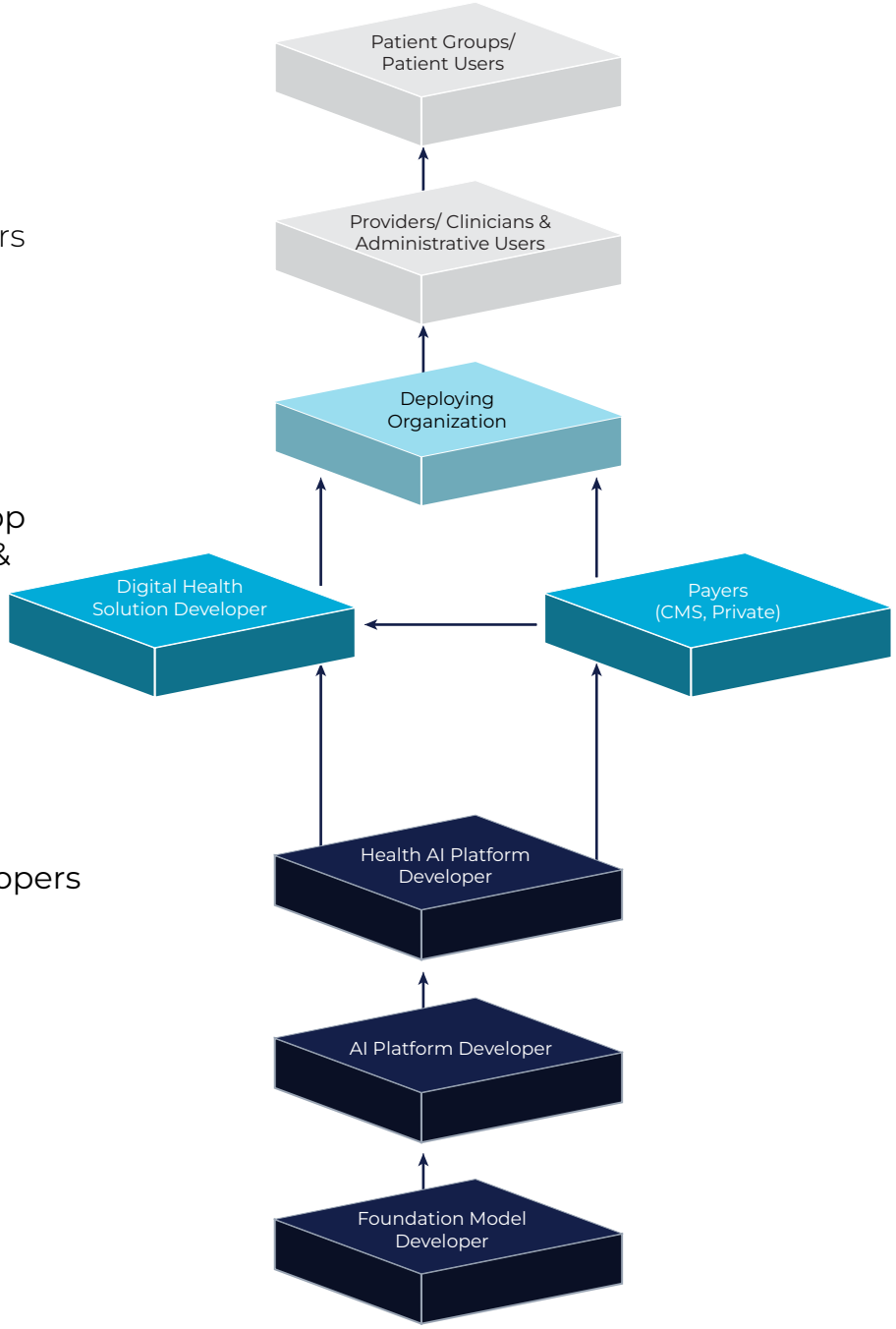
CHI urges all stakeholders in the healthcare ecosystem that are developing and using AI to align with CHI's consensus health AI principles, which recognize the shared responsibility for AI safety, efficacy, and transparency. CHI supports (1) leveraging a risk-based approach to AI harm mitigation where 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, data privacy and security, and equity 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, equity, 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 Actor Tasks
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