

CHI Health AI Roles & Interdependency Framework

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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.



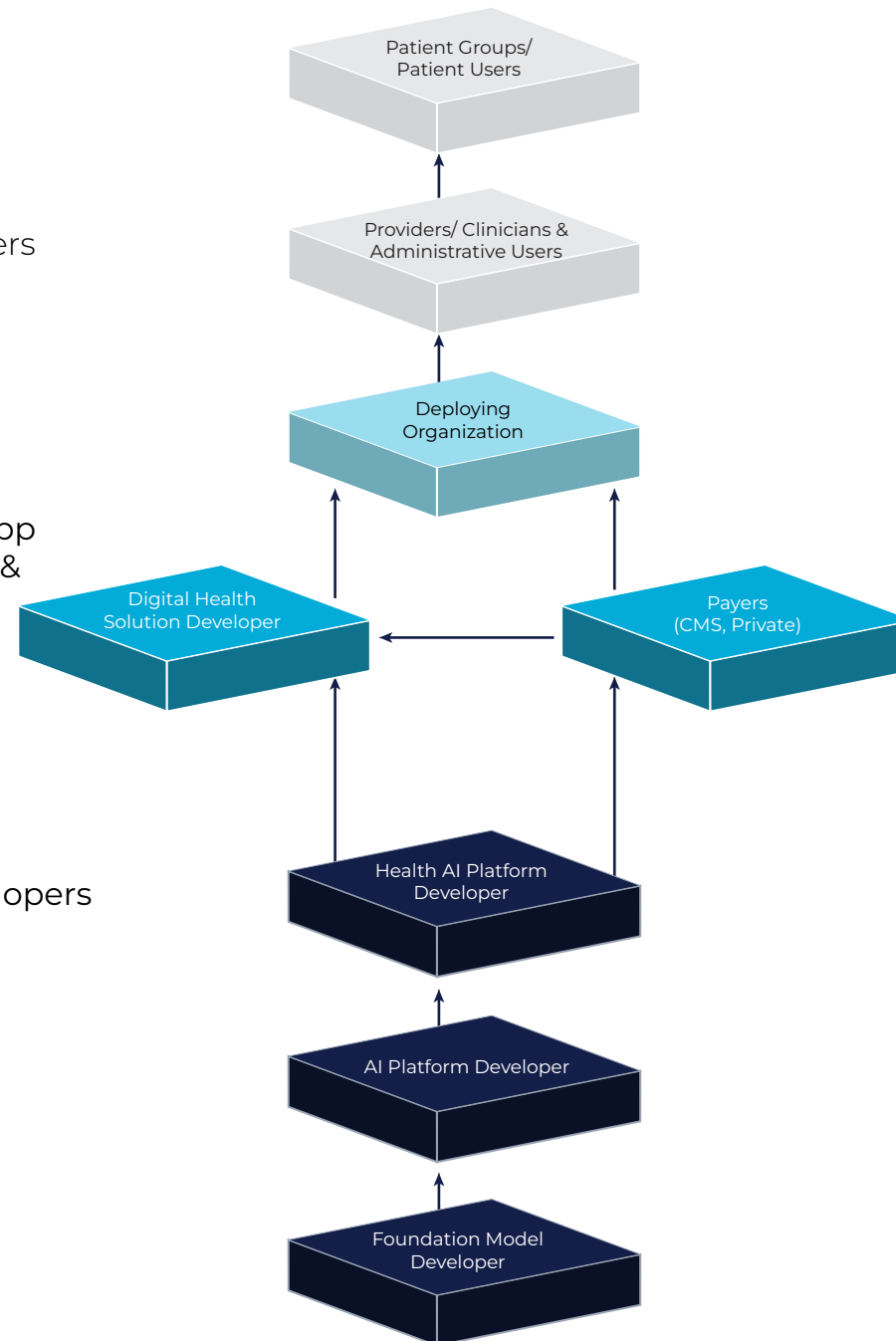
CHI urges all stakeholders in the healthcare ecosystem that are developing and using AI to align with **CHI's consensus health AI principles**, which recognize the shared responsibility for AI safety, efficacy, and transparency. CHI supports (1) leveraging a risk-based approach to AI harm mitigation 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. Where AI outputs inform quality measurement, coverage, or payment, that risk-based approach also means scaling validation and monitoring expectations to the consequences of an error rather than applying a single standard to every tool and every organization.

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

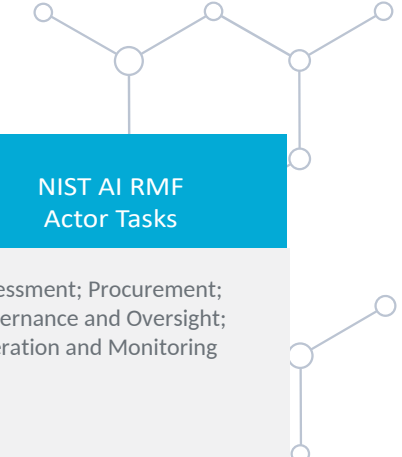
3
AI/ML Developers



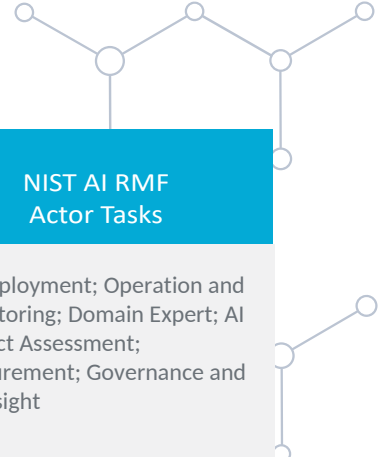
Note: Depending on the use case, some of the roles in the healthcare AI/ML value chain may be occupied by the same party; in other scenarios, some roles may not be occupied.

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. Where a tool's outputs will be used to calculate quality measures, this information should be provided in a form that does not disclose trade secrets. - Prioritizing safety, efficaciousness, transparency, 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, which includes stating whether a model is fixed or continues to learn from new data and how often it will be retested. - 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 to 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. Version information and a description of how a release differs from the one it replaces allow those downstream to judge whether a change warrants revalidation.
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 provider or healthcare payor 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, accounting for the staffing, infrastructure, and licensing a tool will require in practice. - 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, designed so that review stays substantive as use becomes routine). - Developing 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 explanations 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. - Monitoring performance over time as data, documentation practices, and patient populations change, and revalidating after a significant clinical or data infrastructure change, in proportion to what harm an error in a given tool could produce.	Assessment; Procurement; Governance and Oversight; Operation and Monitoring
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 protect against/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. - Where a payer or other entity uses AI-enabled quality measures for payment, public reporting, accreditation, or other accountability purposes, establishing appropriate performance standards, assessing implementation feasibility before widespread use, and monitoring measure performance over time.	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 distributing easy to understand resources that capture how AI/ML is being used and what it means to patients/patient groups, including explanations of 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. - Developing standard formats for the documentation and configuration information developers provide, so that a tool can be documented once rather than once per program or payer, and so that the format can be completed in full without disclosing trade secrets.	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 (e.g., shared reference data sets against which a deploying organization can confirm a tool works in its own environment).	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, including how much clinician review AI-generated information used in quality measurement and reporting warrants in a given specialty.	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, and covering the practical skills local oversight requires (e.g., building a test set and measuring performance). • Developing curriculum to advance the understanding of data science research to help inform ethical bodies (e.g., Institutional Review Boards that review protocols of clinical trials of AI/ML-enabled medical devices).	Human Factors; Domain Expert; AI Impact Assessment