



**Principles for the Use of
Artificial Intelligence in
Health Care and Life
Sciences**



Table of Contents

About Health Innovation Alliance	3
Foreword	4
AI Principles	
Risk-Based	8
Transparent	9
Private	10
Responsible	11
Equitable	12
Acknowledgements	13
Appendix	
Methodology	15
Industry Principles Review	17
Resources	24

About Health Innovation Alliance

The Health Innovation Alliance (HIA) is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of data and technology to improve health outcomes and lower costs.

Formed in 2007, HIA has been on the front lines of federal policy related to healthcare technology and interoperability since our inception. HIA staff and members have helped pass the original Health Information Portability and Accountability Act (HIPAA), helped influence the Health Information Technology for Economic and Clinical Health (HITECH) Act, and helped draft, negotiate, and pass the 21st Century Cures Act.




Foreword

The Health Innovation Alliance is proposing principles for the regulation of artificial intelligence (AI) in health care and life sciences. We have been advocating for the improvement of health care through the commonsense use of data and technology since 2007.

Our organization represents stakeholders across the industry, from some of the largest names in health tech to small and resource-strapped patient advocates, and we work collaboratively with our members to promote consensus policies for adoption by the government.

At the outset of this project, we recognized that there are many opinions, frameworks, and principles already circulating about AI. However, HIA's principles differ in two ways: they are intended to guide Congress and the administration and are focused exclusively on the use of AI in health care.

AI has tremendous potential to relieve many symptoms afflicting the healthcare industry, such as administrative fatigue and rising compliance costs. Providers report increasing burnout and a need to spend nearly half of their time on paperwork or documentation rather than treating patients. AI tools can automate tasks, freeing up caregivers to spend more time in the exam room. HIA believes that technology and data can and will make health care better, and we are hopeful about the role AI will play in improving the lives of providers and patients alike.




Health care is a hyper-regulated industry, and AI has been present in health settings for at least a decade. Existing regulations are already being used to review AI products for use in health care. The Food and Drug Administration (FDA) has approved nearly 900 medical devices that include AI as of July 2024.¹ Despite this, there have been calls to pass new regulations specific to AI. HIA urges Congress to use existing authorities to continue regulating AI in health care and to learn more about the technology, its potential, and its limitations before passing further regulation of AI products.

HIA believes regulation under a risk-based approach is best for AI. The different solutions using AI need to be reviewed on a case-by-case basis: just because an AI model works in one application and setting does not mean it will work in another. AI is just a tool, and it is being adopted in different places under different circumstances by different people. Review of health AI solutions must take all these variables into account. The FDA is already using this type of analysis, and we look forward to working with the FDA, Congress, and others to ensure the advancement of innovative health AI products that are safe and effective.

Finally, government must support the private sector in developing, adopting, and maintaining AI tools in health care. The bipartisan Senate AI work group roadmap released in May 2024 recommends an annual investment of \$32 billion to support non-defense AI innovation, adopting the recommendation of the National Security Council on Artificial Intelligence.² Health care takes up about a third of non-defense spending currently, and HIA recommends that at least \$10 billion of this funding be reserved for AI in health care.

[1] See <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

[2] Available at https://www.young.senate.gov/wp-content/uploads/Roadmap_Electronic1.32pm.pdf



This funding will be needed to promote access to technology and help ensure that health AI is available broadly and not just by organizations with more resources. Healthcare organizations across the country will need support not just in acquiring these technologies, but also in supporting them. The government will need to encourage access to supporting technologies like cloud services and graphics processing units and support the ability of organizations to monitor and maintain AI tools.

HIA is excited about the future of health care, and we look forward to working with Congress and the administration to ensure the commonsense regulation and robust use of AI in the health industry.

AI Principles



Risk-Based

- AI in health care should be regulated according to a context-dependent, risk-based approach.
 - Lower-risk use cases of AI may not require human oversight, particularly when the use case is administrative and has little to no impact on patient outcomes.
 - When used without a human in the loop, the use of AI to diagnose or treat patients is not low risk.



Transparent

- Individuals should have access to information about AI being used in health care, including the AI's intended use and limitations.
 - Patient- or consumer-facing information to improve AI transparency should be accessible to and capable of being easily understood by a reasonably informed individual.
- Transparency requirements in AI should not require the publication of proprietary information or trade secrets.
- Developers of AI should create documentation sufficient to inform users about the tools. This documentation should include information about fairness, bias, privacy, security, intended use constraints, necessary oversight requirements, and functionality limitations.
- Regulators should be able to assess AI models intended for use in health care to determine safety, effectiveness, reliability, and limitations.
 - In the event a regulator believes information is required for an assessment that an AI developer maintains is proprietary, the regulator must provide reasonable safeguards and protections to preserve confidentiality.
 - Information required to assess an AI model deployed or intended for deployment in health care should be reasonably limited to the purpose of that particular assessment.



Private

- AI use of health information should be compliant with all applicable privacy and security laws and regulations, such as the rules promulgated under HIPAA, and should follow patient preference through existing authorization and consent processes.
- Use of identifiable health information to train an AI model should be authorized by the individual through existing consent requirements.



Responsible

- Both developers and deployers should adopt and adhere to responsible and reasonable best practices throughout the development and deployment of AI models in health care.
- Government should work with the AI developers and deployers to encourage the development and adoption of AI best practices and processes.
- Developers of AI models for use in health care should participate in the development and coordination of best practices for the responsible use of AI models.
- Deployers of AI in health care should be responsible for the use of the AI models they deploy.
 - This includes testing of a model within the intended environment, on intended populations, for the intended use case, and;
 - Appropriately monitoring the models in use and implementing any necessary safeguards.



Equitable

- Developers and deployers of AI in health care should take reasonable effort to mitigate bias, and where possible, remove bias.
- AI should be tested in the environment and population intended for its use and monitored for bias and inequity while in use.
- AI should be accessible and usable by the entire health care community – not just those who can afford it.
 - Government should provide resources to encourage the adoption, deployment, and use of AI in health care, including supporting technologies and services, to facilitate equitable adoption.
 - Government should provide resources for both the development of best practices and management protocols as well the adoption, implementation, and management of those best practices and management protocols in health care.

Acknowledgements

These principles were made possible through the substantial contributions and thoughtful discussion of the workgroup members. While participation in the workgroup does not imply affiliation with or endorsement of the recommendations in this report, HIA wishes to thank the following organizations who participated in the AI Workgroup process:

- Association of Behavioral Health and Wellness
- The Association of Clinical Research Organizations
- Altitude Ventures
- Amazon
- AstraZeneca
- athenahealth
- Autoimmune Association
- Avalon Healthcare Solutions
- Cambia Health Solutions
- Cancer Support Community
- CoverMyMeds
- Consumer Technology Association
- Digital Medicine Society
- Duke AI Health
- GO2 For Lung Cancer
- Greystone Group
- Healthcare Information and Management Systems Society
- iRhythm Technologies
- Maven Clinic
- Maverick Health Policy
- McKesson
- National Multiple Sclerosis Society
- National Council for Prescription Drug Programs
- Partnership to Fight Chronic Disease
- RELX
- STChealth
- Teladoc Health
- Tempus
- The Joint Commission
- The National Council for Mental Wellbeing
- United Spinal Association
- US Chamber of Commerce

Appendix

Methodology


HIA held two workgroup meetings and numerous individual discussions over the first half of 2024, with more than 30 different participating organizations. Participants represented solutions providers, established tech companies, tech startups, patient advocates, pharmaceutical manufacturers, provider organizations, and others.

The purpose of the workgroup was to produce a set of principles for the use of AI in health care and life sciences. HIA staff proposed five subcategories, based on a review of existing AI frameworks, through which principles could be formatted: transparent, risk-based, private, responsible, and equitable.

During the first meeting in February 2024, participants raised several points within each category for consideration. Participants agreed that existing regimes such as HIPAA may be sufficient to adequately regulate AI, though other considerations on informing patients, and ensuring copyright protections and data ownership are necessary. There was also agreement that a risk-based approach would be best to manage and regulate AI, but significant attention would be needed to develop and deploy AI models responsibly and minimize bias.

The second meeting of the workgroup was held on March 21, 2024. HIA staff reviewed existing principles for AI and created a summary document to help inform the workgroup. We reviewed and discussed AI principles from outside organizations during this meeting.

Participants also discussed the types of information needed by patients and regulators to understand and oversee AI tools, respectively, and how risk levels vary with clinical uses of AI. There was again agreement that HIPAA is sufficient to address privacy concerns, though de-identification of data and internal governance are key considerations.



A recurring theme was the need to monitor AI models for drift to avoid bias, and that data selection affects the development and may limit the breadth of final use cases.


On June 4, 2024, HIA staff introduced an initial draft principles document based on the discussion and feedback from participants throughout the workgroup process. After robust feedback and discussion with participants, HIA crafted the principles included here.

Industry Principles Review

The following is a review of AI principles released by various organizations within or relevant to the health care community. The purpose of this document is to catalog publicly available positioning on health care AI to inform the workgroup. This list is not exhaustive, and some information may be outdated. The following is an interpretive summary and is not intended to directly represent the thinking of any organizations listed or to be an endorsement of any specific position by any of the organizations listed.

The chart below reflects which organizations principles or best practices touched on each of the listed topic areas.

Breakdown				
Transparency	Risk-Based	Private	Responsible	Equitable
AAFP	AAFP	AAF	AAFP	AAFP
ACRO	ACRO	AdvaMed	ACRO	ACRO
AMA	AMA	ATA	AMA	AdvaMed
ATA	ATA	AWS	ATA	AMA
AWS	AWS	BastionGPT	AWS	ATA
BastionGPT	BastionGPT	Biden EO	BastionGPT	AWS
CHI	CHI	CHI	Biden EO	Biden EO
EU AI Act	EU AI Act	IFPMA	Forbes	CHI
Forbes	Forbes	Merck	IFPMA	Google
IFPMA	IFPMA	Microsoft	Merck	IFPMA
Merck	Merck	Optum	Microsoft	Merck
Microsoft	Microsoft	OSTP	ONC	Microsoft
ONC	ONC	Pfizer	Optum	Optum
Optum	Optum	RELX	Philips	OSTP
OSTP	Philips	Roche	Roche	Pfizer
Pfizer	RELX	WHO	WHO	Philips
Philips	Roche			RELX
RELX	WHO			Roche
Roche				WHO
WHO				



Organizations included:

- American Academy of Family Physicians (AAFP)
- Association of Clinical Research Organizations (ACRO)
- AdvaMed
- American Medical Association (AMA)
- American Telemedicine Association (ATA)
- Amazon Web Services (AWS)
- BastionGPT
- President Biden Executive Order on AI (Biden EO)
- Connected Health Initiative (CHI)
- European Union AI Act (EU AI Act)
- Forbes
- Google
- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- Merck
- Microsoft
- Office of the National Coordinator for Health Information Technology (ONC)
- Optum
- White House Office of Science and Technology Policy (OSTP)
- Pfizer
- Philips
- RELX
- Roche
- World Health Organization (WHO)

Transparency

Major Themes			
Governance & Best Practice	Inform that AI is Used	Disclose/Publish Inner Workings	External Oversight & Review
<p><i>AMA, AWS, EU, ONC, RELX</i></p> <p>—</p> <p>governance policies are necessary, best practices also helpful</p>	<p><i>ACRO, AWS, Google, IFPMA, Merck, Microsoft ONC, Philips, RELX, Roche, WHO</i></p> <p>—</p> <p>Disclose how AI is used in a process, inform about AI-generated content.</p>	<p><i>AAFP, ATA, AWS, Forbes, Microsoft, RELX</i></p> <p>—</p> <p>Disclose how data is processed, how algorithms developed, design system to enable that.</p>	<p><i>AWS, BastionGPT, CHI, RELX, Roche, WHO</i></p> <p>—</p> <p>All think that there should be healthcare/ other experts vigilant/reviewing.</p>
		<p>[<u>similar thought, but all don't say the above</u>]</p> <p><i>IFPMA, OSTP, Pfizer,</i></p> <p>—</p> <p>End-user must understand how they are impacted, understand limitations.</p>	<p><i>OSTP</i></p> <p>—</p> <p>Goes further to say independent evaluation is needed.</p>

Risk-Based

Major Themes			
Risk-based Approach	Oversight, Testing, Compliance	Patient Safety	Cybersecurity, Data Security
<p><i>AAFP, AMA, CHI, EU, Merck, RELX</i></p> <p>—</p> <p>Agreement on risk-based approach in some capacity</p>	<p><i>ACRO, BastionGPT, Forbes, Merck, Microsoft, Optum, Philips, RELX, Roche, WHO</i></p> <p>—</p> <p>Human oversight necessary</p>	<p><i>BastionGPT</i></p> <p>—</p> <p>No communication with patients unless very strictly controlled.</p>	<p><i>WHO</i></p> <p>—</p> <p>Cybersecurity and safety of data takes precedence.</p>
<p><i>AAFP</i></p> <p>—</p> <p>Companies should take on liability based on the risk, accounting for role of AI/ML in the process</p>	<p><i>AMA, AWS, IFPMA</i></p> <p>—</p> <p>Level of oversight should be proportionate to risk</p>	<p><i>Merck, RELX</i></p> <p>—</p> <p>Goal of all systems to benefit people without harm.</p>	<p><i>RELX</i></p> <p>—</p> <p>We respect privacy champion robust data governance</p>
<p><i>Microsoft, RELX</i></p> <p>—</p> <p>Impact assessment on our AI, oversight of significant adverse impacts, data/management practices.</p>	<p><i>Microsoft, Optum, OSTP, RELX</i></p> <p>—</p> <p>Emphasis on testing before deployment and afterward</p>		
<p><i>AWS, RELX</i></p> <p>—</p> <p>Organization's role to define, implement, and enforce responsible AI practices</p>	<p><i>ATA</i></p> <p>—</p> <p>Clear regulation and uniform compliance</p>		

Private

Privacy of Patients/Users	Health System Policies	Consent	Built-In Privacy Protections
<p><i>AAF, AdvaMed, BastionGPT, CHI, IFPMA, Merck, Microsoft, Pfizer, WHO</i></p> <p>—</p> <p>Agree privacy is needed to protect patients. Never compromised.</p>	<p><i>CHI</i></p> <p>—</p> <p>Modern privacy framework</p>	<p><i>AAFP, CHI, Google, OSTP, WHO</i></p> <p>—</p> <p>Consent in use of Data with AI</p>	<p><i>AWS, Google, Microsoft, Optum, OSTP, Pfizer, RELX</i></p> <p>—</p> <p>Incorporate privacy practices into AI Systems/Policies</p>
<p><i>Optum, OSTP, Biden EO, Roche</i></p> <p>—</p> <p>Protect data privacy, but no mention of patients.</p>	<p><i>WHO</i></p> <p>—</p> <p>Adopt new legal frameworks</p>		
<p><i>AWS, RELX</i></p> <p>—</p> <p>Data protected from theft and exposure (all uses)</p>	<p><i>ATA, BastionGPT, IFPMA</i></p> <p>—</p> <p>Utilize current system policies/regulations.</p>		

Responsible

Development & Deployment	Organizational Accountability	Responsible Advancement of AI	Governance
<p><i>AMA, AWS, Biden EO, Google, Merck, Microsoft, WHO, RELX</i></p> <p align="center">—</p> <p>Agree that responsible development and deployment is necessary to ensure safety</p>	<p><i>AAFP, ACRO, ATA, AWS, Google, IFPMA, Merck, Microsoft, Optum, RELX, Roche, WHO</i></p> <p align="center">—</p> <p>It is the organization’s responsibility to maintain rigorous evaluation of AI/ML safety.</p>	<p><i>AWS, Biden EO, Merck, RELX</i></p> <p align="center">—</p> <p>Build policies that ensure responsible innovation and use of AI/ML</p>	<p><i>AMA, Optum</i></p> <p align="center">—</p> <p>Develop a national governance applying to all AI/ML Solutions</p>
<p><i>ONC</i></p> <p align="center">—</p> <p>Fair, Appropriate, Valid, Effective, Safe (FAVES) principles in deployment</p>			<p><i>AWS, ACRO, Google, Merck, RELX, Roche</i></p> <p align="center">—</p> <p>Organizations should develop their own governance teams</p>
<p><i>ACRO</i></p> <p align="center">—</p> <p>Orgs develop teams to govern Dev. & Deployment.</p>			

Equitable

Reduce Bias in Design + Development	Use AI to Reduce Inequities	AI should be Ethical
<p><i>ACRO, AAFP, AdvaMed, AMA, ATA, AWS, CHI, Google, IFPMA, Merck, Microsoft, Optum, OSTP, Pfizer, Philips, RELX, Roche, WHO</i></p> <p>—</p> <p>Avoid bias in design and development</p>	<p><i>Biden EO, Google,</i></p> <p>—</p> <p>Don't exacerbate existing inequities</p>	<p><i>General Agreement</i></p> <p>—</p> <p>AI design, deployment, and use should be ethical</p>
<p><i>AAFP, CHI, IFPMA, Philips, RELX, Roche</i></p> <p>—</p> <p>Training data should be diverse and representative.</p>	<p><i>AMA, AWS, RELX</i></p> <p>—</p> <p>Avoid bias in deployment and use</p>	
<p><i>ATA, AWS, RELX</i></p> <p>—</p> <p>Make publicly available information to show algorithms and outputs are free from bias. Perhaps necessary for policy for transparent exposure of bias.</p>	<p><i>AdvaMed, Optum</i></p> <p>—</p> <p>Reduce health disparities</p>	
<p><i>Optum</i></p> <p>—</p> <p>Designers, developers and deployers must protect from algorithmic discrimination</p>	<p><i>Pfizer</i></p> <p>—</p> <p>Actively design and use AI systems to promote equity</p>	

Resources

ACRO: <https://www.acrohealth.org/wp-content/uploads/2023/12/ACRO-AI-Principles-Final.pdf>

AAFP: <https://www.aafp.org/about/policies/all/ethical-ai.html>

AMA: [AMA Principles for Augmented Intelligence Development, Deployment, and Use \(ama-assn.org\)](https://www.ama-assn.org/practice-management/ai-principles)

ATA: [AMERICAN TELEMEDICINE ASSOCIATION PUBLISHES NEW ARTIFICIAL INTELLIGENCE \(AI\) PRINCIPLES - ATA](https://www.american-telemedicine.com/ata-ai-principles)

AWS: <https://aws.amazon.com/machine-learning/responsible-ai/>

BastionGPT: [Generative AI Healthcare Principles \(bastiongpt.com\)](https://bastiongpt.com/generative-ai-healthcare-principles)

ConnectedHealth Initiative (CHI): [Policy-Principles-for-AI.pdf \(connectedhi.com\)](https://connectedhi.com/policy-principles-for-ai)

European Union AI Act: [The Act Texts | EU Artificial Intelligence Act](https://eur-lex.europa.eu/eli/reg/2024/418/oj)

Forbes Walter Kluwer Four Guiding Principles for Generative AI: [Do No Harm: Four Principles For Adopting Generative AI In Healthcare \(forbes.com\)](https://www.forbes.com/sites/walterkluwer/2023/04/27/do-no-harm-four-principles-for-adopting-generative-ai-in-healthcare/)

Google: <https://ai.google/responsibility/principles/>

IFPMA: [IFPMA Artificial Intelligence Principles - IFPMA](https://www.ifpma.org/ai-principles)

Merck: [AI_MRK_MAY23docx.pdf \(merck.com\)](https://www.merck.com/ai-principles)

Microsoft: [Responsible AI Principles and Approach | Microsoft AI](https://www.microsoft.com/ai/responsible-ai)

ONC Health Sector Commitments: https://www.healthit.gov/sites/default/files/2023-12/Health_Sector_AI_Commitments_FINAL_120923.pdf

Optum Responsible Use of AI: [Ensuring Responsible Use of AI in Health Care | Optum](https://www.optum.com/ai-principles)

OSTP AI Bill of Rights: <https://www.whitehouse.gov/ostp/ai-bill-of-rights/>

Pfizer Principles: [Artificial Intelligence \(AI\) Responsibility in Healthcare is Critical | Pfizer](https://www.pfizer.com/ai-principles)

Philips 5 Guiding Principles for Responsible Use of Ai in Healthcare and Healthy Living: [Five guiding principles for responsible use of AI in healthcare and healthy living - Blog | Philips](https://www.philips.com/ai-principles)

RELX: [relx-responsible-ai-principles-0622.pdf](https://www.relx.com/ai-principles)

Roche: [Roche AI Ethics Principles-UX formatted](https://www.roche.com/ai-principles)

WHO Ethics and Governance of AI for Health: [Ethics and governance of artificial intelligence for health \(who.int\)](https://www.who.int/ai-ethics)



HEALTH INNOVATION
ALLIANCE

440 1st Street NW, Suite 430
Washington, DC 20001
202.643.8645

Health-Innovation.org
@HIA_DC