

Policy Principles: Artificial Intelligence and Machine Learning

Preamble

To accelerate digital health transformation, we must foster seamless, secure, ubiquitous, and systemwide data access and interoperable health information exchange. Interoperable data exchange ensures the right people have the right access to the right health information in a usable format at the right time to deliver optimal care. Health information and technology serve as the catalyst for transforming the health ecosystem, modernizing care delivery, driving health innovation, and enabling health research.

Artificial intelligence and machine learning (AI/ML) drives numerous applications that can improve patient care, improve early detection of disease and enhance point of care and administrative efficiency. AI/ML tools are critical resources to driving innovation and digital transformation.

Policies should promote and accelerate the responsible governance and deployment of AI demonstrated to benefit stakeholders in the health and human services sector and ensure that AI is continually monitored and revalidated following deployment in the field.

Principles

Safe and Trusted AI/ML

1. **Policy Guardrails:** AI/ML policy guardrails should have two primary areas of focus: the development, initial deployment and use of AI/ML, and the evolution of AI/ML once the tools have been deployed and evolves as they ingest data.
2. **Feasibility Testing/Equity Bias Mitigation:** Rigorous pre-release feasibility testing and post-deployment monitoring of outputs of AI/ML technologies should be completed to ensure that AI/ML will, at a minimum, not amplify harmful biases, and at best help to address any biases already inherent in healthcare data. Policies should drive towards the use of training data which is appropriately inclusive and representative of the patient populations where the AI/ML tool is intended to be deployed.

3. **Clinician and Consumer Trust:** Maximizing the benefits of AI-enabled tools in a clinical environment requires building and maintaining clinician and consumer trust. Trust is based on a sufficient understanding of the tool and its intended use to satisfy clinicians' desires for fairness and equity in AI tool's application. HIMSS calls for requirements that AI tools provide appropriate explainability to their users and/or sufficient and ongoing evidence of fair and robust performance within a specific population to ensure the trust of its users is maintained.
4. **Monitor and Evaluate AI Performance:** Appropriate governance requires thoughtful action and monitoring by all parties, from market suppliers to hospitals to providers. Policy should require the use of technologies including AI/ML tools to evaluate and monitor AI/ML model performance and provide feedback to the developers (foundation model developers and developers/tools that incorporate the foundational model) and end-users of the AI/ML tool.
5. **Feedback Loop:** Regulatory frameworks should create easy to use standardized channels for end users, patients, and care givers to provide feedback to policymakers and developers provide on the results of real-world application of the model, and/or to report that the AI/ML does not perform as expected. Policymakers should consistently solicit and review feedback from public and private sectors to assess AI/ML technologies and identify opportunities to evolve legal and regulatory frameworks as new legal guardrails are needed.

Transparency and Patient Privacy

6. **Protecting Patient Data:** Policymakers should conduct extensive review of current privacy frameworks and extend those frameworks to specifically address AI and ML. Where gaps exist, privacy, disclosure, and consent standards specific to evolving AI/ML technologies should be developed to serve as explicit guidance for how patients' information is shared and used. These standards should support the capacity of individuals to restrict the sharing of personal confidential information.
7. **Human Oversight and Transparency:** Clinical decisions involving or influenced by AI/ML should be made collaboratively between humans and technology, to the extent necessary to preserve patient autonomy and comfort and improve clinical care outcomes. Providers should use tools that are determined safe and appropriate by governing bodies to provide the highest quality clinical care, including AI-enabled systems. If fully autonomous systems that make independent decisions in patient care will be used, patients should be informed prior to receiving care enabled by these systems.

Interoperability and Data Harmonization

8. **Data Harmonization** Policymakers should facilitate the development of standards and harmonization to ensure AI/ML technologies can appropriately exchange data and

learning across different healthcare systems and be seamlessly integrated into existing workflows.

9. **Deidentified Data's Role in Research:** AI/ML data governance and stewardship models should be developed and regularly updated to promote the authorized use and disclosure of data and account for use case fidelity and model development, monitoring, and operations. AI/ML data governance and stewardship models should incorporate guidelines for international data-sharing and consider the varying data protection laws across countries.

Workforce and Sustainability

10. **Workforce Development:** Policies should support adding the skillsets and knowledge needed for a clinical and IT support workforce focused on testing, monitoring, and revalidating AI/ML following deployment in the field.
11. **Sustainability and Environmental Impact:** Any AI/ML focused regulatory framework should consider the environmental impact of the model's use, promoting sustainability in healthcare technology advancements and include guidelines to minimize the environmental impact of AI systems by encouraging energy-efficient algorithms to reduce the carbon footprint of AI technologies. Additionally, the adoption of AI/ML models that reduce energy consumption and minimize environmental impact should be incentivized. Regular AI/ML technology lifecycle assessments should be conducted to determine energy consumption and environmental impact.