



Principles for Artificial Intelligence in Medical Technology



Artificial intelligence (AI) applied to medical technology has and will continue to transform patient care. These advancements can enable physicians to better understand diseases, achieve faster, more accurate diagnostic results, and determine appropriate treatment pathways. The FDA has reviewed and authorized more than 600 artificial intelligence- and machine learning-enabled medical devices since 1995, with rapid advancements anticipated in the coming years. The following principles will guide further innovations, policymaking, and regulations in AI-enabled medical technology.

Principle: Promoting the adoption and development of AI technologies to serve patients.

Considerations: Public policy and regulation should promote patient access to innovative health care AI technologies. These regulations and policies should reflect a comprehensive understanding of the technology development and use, resulting from robust communication and collaboration among legislators, regulators, device innovators, health practitioners, patients, and other stakeholders.

The FDA has and will continue to play a vital leadership role in regulating AI-enabled medical devices, as it does with all medical technology, and Congress will maintain appropriate oversight regarding AI technology policy needs.

Principle: Using AI to facilitate and promote access to health care in rural and other under-served communities.

Considerations: The deployment and use of AI-enabled technologies by physicians and hospitals can enable improved access to care in rural and underserved patient communities. These innovations may make critical technology more accessible to more health care facilities and may enable health care providers to serve greater numbers of patients. For example, certain AI applications can streamline workflow, bringing efficiencies to health care practices facing resource constraints.

Resources, including guidelines developed by consensus through expert institutions, can be useful in evaluating and deploying AI-enabled technology in rural and under-served communities. Policymakers, regulators, industry, and other stakeholder groups should promote distribution of and access to AI-enabled devices to benefit these patients.

Principle: Educating the public on the role and value of AI medical technologies.

Considerations: Numerous surveys show the public has an incomplete understanding of AI and its numerous applications. Public trust in the use of AI in medical technology also varies. Some survey respondents fear AI will replace their doctors, nurses, and specialists. Other respondents express concern that AI will compromise patient privacy; cause mistakes in diagnosis or treatment; or is being deployed too rapidly in health care. Additional respondents consider AI's application in health care too slow or small to make a difference in their care.

Informing patients about how and where practitioners are using AI-enabled medical technology in their care and to what extent the technology enhances the patient experience is critical to building the trust necessary for AI to fulfill its tremendous potential in medicine. This effort requires education from all entities involved directly in or influencing the patient experience.

Principle: Develop and deploy AI solutions using high-quality, robust, and clinically relevant data to identify, mitigate, and educate on potential bias and discrimination in AI-enabled devices.

Considerations: AI-enabled technology relies on data sets to build, train, and tune algorithms. Large, diverse, and representative data sets facilitate robust algorithm development and can help identify and mitigate unwanted bias. Device manufacturers mitigate bias and discrimination in AI products by careful and thorough data collection, analysis and curation and the ongoing evaluation and validation included in the FDA regulatory review process.

Principle: Adoption of AI technologies will require appropriate incentives for health care providers.

Considerations: A lack of consistent and reliable payment policies will discourage research and development investment and will ultimately hamper adoption of AI health care technology. Many AI technologies are services that produce clinical outputs that aid clinicians in the diagnosis or treatment of a patient's condition and provide analysis that cannot be obtained by the health care provider alone. Policymakers should ensure that this value is appropriately captured in payment systems.

Principle: Protecting patient privacy and data security.

Considerations: The safeguarding of patient data is critical in any health care application, including medical technology using AI software and systems. AI-enabled medical technology must protect patient privacy and secure patient data from the outset. Users must handle all patient information responsibly and in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and other laws. Users also must protect AI-enabled systems against cybersecurity threats, drawing on guidance and best practices, such as the American Medical Association's [Privacy Principles](#).

Principle: Ensuring training in AI-enabled technology.

Considerations: As with any new medical technology, AI-enabled devices require robust training to ensure clinicians are properly trained in deploying the devices for patient benefit. For example, clinicians should not presume AI supplants their knowledge and judgment in making diagnoses. AI is a tool used in the clinician-led practice of medicine, not to supplant clinical expertise.

