Principles for Artificial Intelligence in Medical and Digital Health Technologies

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Artificial intelligence (AI) driven by innovative medical technology has and will continue to transform healthcare. Advancements can enable clinicians to better understand diseases, achieve faster and more accurate diagnoses, and leverage more information than ever before to develop appropriate treatment options and care plans. AI-enabled technologies can also streamline workflows and other administrative tasks, bringing efficiencies to health care practices that face resource constraints and clinician burn out.

This document provides foundational principles for the development and deployment of AI/ML-enabled healthcare products. The entire healthcare ecosystem should be aware of the opportunity to better serve patients while sharing in the commitment to protect safety, security, and privacy through responsible development of AI. These stakeholders include, but are not limited to patients, healthcare professionals, healthcare providers, IT system integrators, Health IT developers, IT vendors, medical device manufacturers, and regulators.

Principle: Leverage existing regulatory frameworks and promote international alignment to ensure timely patient access to innovative AI/ML-enabled medical technologies.

Considerations: FDA has a comprehensive regulatory framework that ensures the safety and effectiveness of many different types of medical technologies across the total product lifecycle (i.e., premarket and postmarket). The current premarket and postmarket regulatory frameworks are fully able to ensure the safety and effectiveness of AI/ML-enabled devices, whether they use locked or adaptive AI algorithms. As of August 2024, FDA has authorized over 950 AI/ML-enabled medical devices[1]. FDA's oversight is guided by a risk-based framework that includes a rigorous premarket review process that assesses medical device performance, reliability, and safety, as well as extensive postmarket monitoring and surveillance requirements after devices are authorized for sale. The FDA has the authority to regulate emerging AI/ML technologies, and the current regulatory frameworks, which includes the Predetermined Change Control Plan (PCCP) authorities[2], are sufficient to ensure the safety and effectiveness of these devices.

FDA must ensure the tools and processes it has under its existing authority are implemented and, where appropriate, adapted to keep pace with emerging technologies, such as generative AI. For example, the PCCP framework could be adapted to allow for appropriate guardrails within the premarket authorization which would allow for postmarket modifications for adaptive algorithms. This would maintain safety and effectiveness without creating barriers to realizing the full potential of these

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

[2] On December 29, 2022, section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 ("FDORA") added section 515C "Predetermined Change Control Plans for Devices" to the Federal Food, Drug, and Cosmetic (FD&C) Act. Section 515C of the FD&C Act (21 U.S.C. 360e-4) has provisions regarding predetermined change control plans (PCCPs) for devices requiring premarket approval (PMA) or premarket notification (510(k)).

technologies for patients. As AI/ML technology matures, international voluntary consensus standards specific to medical devices should be the foundation for safe, effective, and responsible development and deployment. It is critical that FDA prioritize the development, revision, and timely recognition of such standards to promote industry-wide adoption of AI/ML best practices. A focus on international voluntary consensus standards would also support consistency in the Agency's expectations for AI/ML-enabled medical technologies. The Agency should also continue to prioritize federal, state, and international collaboration to help further innovation and promote alignment and consistency in approach.

Principle: Protect privacy of patient data with transparency and consent.

Considerations: The data required to build AI models and deliver AI-enabled solutions should be collected transparently with appropriate informed notice and authorization. Technology innovators should protect patient privacy in compliance with all applicable data privacy laws and regulations and implement industry best practices, international consensus standards, and organizational measures to ensure data security, integrity, and confidentiality. 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. ***See also: AdvaMed U.S. Health Data Privacy Principles (2020)***

Principle: Enable access to data and utilization for the benefit of patients.

Considerations: There should be a clear definition of which stakeholders may access patient data and for what purpose(s). Adherence to the highest ethical and trustworthy standards in management of data should be prioritized. Healthcare stakeholders, innovator personnel, and external vendors should collaborate to deliver a clear understanding about what data is collected, how it is being used, and how it is being protected. Individuals should have appropriate control and transparency over their data consistent with legal and regulatory requirements. ***See also: AdvaMed Principles for Data Access & Utilization in Medical and Digital Health Technologies (2024)***

Principle: Develop and deploy AI/ML-enabled solutions responsibly and mitigate against unwanted bias in AI/ML-enabled medical technologies.

Considerations: Bias is a potential consideration for many types of medical technologies and is not unique to AI/ML algorithms. Bias can be positive or negative. Some bias is introduced intentionally because it is beneficial to the intended patient population. For example, an algorithm designed to prioritize early cancer detection in high-risk groups, such as older adults or individuals with a family history of the disease, may intentionally focus on this population to improve outcomes. As with all medical technologies, it is important for manufacturers to identify and mitigate unwanted bias, which can lead to discrimination, in AI/ML-enabled medical technologies.

FDA enforces oversight on the development, testing, authorization, and postmarket requirements of AI/ML-enabled devices. To identify and address potential unwanted bias in AI-enabled devices, high-quality and representative data sets of the target patient groups are essential. Manufacturers can mitigate unwanted bias prior to product release through careful and thorough data collection, analysis,

and curation. FDA's premarket review includes an evaluation of unwanted bias and an assessment of the appropriateness of the mitigation to ensure AI/ML-enabled devices are safe and effective for the intended population. Once on the market, ongoing monitoring, evaluation, and/or validation may be needed. Manufacturers are responsible for postmarket requirements after deployment, and for reporting problems to the FDA to ensure continued safety and effectiveness.

Principle: Promote access to and the adoption of AI technologies to serve patients.

Considerations: Patients and health consumers have consistently sought the most advanced technologies from innovators and health care professionals. The current CMS reimbursement framework is based on a statutory foundation that did not contemplate the need to capture coverage, coding, or payment for these types of new diagnostics and therapeutic technologies, including algorithm-based healthcare services (ABHS). As a result, the reimbursement framework is inconsistent and unreliable to meet the needs of patients. A lack of consistent and reliable payment policies hamper research and development investment, risking that healthcare innovation will fail to keep up with advances in other economic sectors. Reimbursement frameworks should be established to capture the full value of new AI-enabled technologies, including the long-term financial savings associated with better health outcomes and earlier detection of diseases and the efficiencies gained by healthcare providers. ***See also: AdvaMed* Principles for Enhancing Patient and Provider Access to Digital Health Technologies *(2024)***

Principle: Leverage AI-enabled and digital health solutions to facilitate and promote access to health care in rural and under-served communities to improve health equity.

Considerations: The deployment and use of AI-enabled and digital health technologies by clinicians and health care providers should be extended to improve access to care in rural and underserved patient communities. The expansion and extension of these technologies can bring otherwise inaccessible clinical expertise to unique populations, while better supporting clinician workload management to engage, diagnose and treat larger volumes of patients outside of the clinical environment. The continued emergence of more sophisticated diagnostics and therapy solutions, such as prescription digital therapeutics, deliver remote solution opportunities to significantly impact health equity challenges.

Principle: Educate the public, patients, and clinicians on the roles and value of AI/ML-enabled health technologies while prioritizing clinician and user training in AI/ML-enabled technologies.

Considerations: Public trust in the use of AI in healthcare and medical technology varies, although interest in seeing greater innovation and a willingness to utilize these technologies is increasing. Effectively communicating the benefits of these technologies to patients and caregivers, along with how and where practitioners are using them in patient care, is essential for building comfort and trust. This effort requires collaboration among innovators, care providers, stakeholders, and policymakers.

AI is a new and powerful tool for clinicians and should not be seen as a replacement for the practice of medicine or the administration of healthcare. As with any new medical or health technology, users often benefit from robust training. Clinicians should be well educated on how to deploy the technologies for maximum patient benefit.

Principle: Deliver transparency, essential to patient-centered care, that contains the appropriate level of information necessary to ensure the safe and effective use of the device.

Considerations: Transparency is a key aspect of trustworthy AI. Transparency can help improve accountability, the safe and effective use of AI/ML-enabled technologies, and help users make informed decisions. Providing for appropriate transparency can foster trust and encourage adoption of the technology.

Transparency should be focused on essential and meaningful information that is needed to establish the safety and effectiveness of the device and what is needed to best support the end user. When considering transparency and explainability[3] of AI-enabled technologies within medical devices, it is important that this information is meaningful to users, however, it is also important the content does not compromise on performance of AL/ML-enabled devices purely to provide explainability. FDA's existing labeling frameworks for medical devices provide an effective mechanism for manufacturers to communicate the essential information needed for the safe and effective use of AI-enabled technologies. Specifically, this labeling framework ensures that product information is provided in a clear and timely manner and shared in a way that best supports patients and health care professionals in understanding the benefits, risks, and limitations to safe and effective use of the product.

[3] From the FDA/Health Canada/MHRA Principles: " 'transparency' describes the degree to which appropriate information about a MLMD (including its intended use, development, performance and, when available, logic) is clearly communicated to relevant audiences"… "The degree to which …logic can be explained in a way that a person can understand is known as 'explainability'"… "'Logic' refers to information about how an output or result was reached or the basis for a decision or action." (https://www.fda.gov/media/179269/download?attachment)