Artificial Intelligence in Medical Technology Myths vs. Facts

Artificial intelligence (AI) and its subset, machine learning (ML), are expanding in multiple applications, including medical technology. Outlining the facts and dispelling myths will inform policymaking to avoid overlap with current regulations and preserve the broad capacity of innovation to help patients.

Myth: The use of AI/ML technology is unregulated and new to medical devices.

Fact: FDA has been reviewing and authorizing AI/ML-enabled medical devices for nearly 30 years. FDA approved the first medical device incorporating AI/ML technology in 1995. To date, FDA has authorized more than 600 AI/ML-enabled medical devices. Most of these devices are radiology devices (e.g., image analysis), but there are authorized devices in other medical specialties such as cardiovascular and neurology.

AI/ML-enabled devices are subject to the same premarket regulatory pathways and FDA regulatory oversight as all other medical devices. FDA assesses the safety and effectiveness of AI/ML algorithms, considering factors like data quality, robustness, and clinical performance. The majority of the FDA- authorized AI/ML-enabled devices were cleared through the 510(k) pathway for lower- and medium-risk devices. Post-market regulations and requirements also apply (e.g., adverse event reporting, quality control systems).

The FDA and the medical device industry recognize the value of globally harmonized approaches to the regulation of AI/ML-enabled devices. In 2021, the FDA, Health Canada, and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) jointly issued a document identifying 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP). GMLP supports the development of safe, effective, and high-quality artificial intelligence/machine learning technologies that can learn from real-world use and potentially improve device performance.

In October 2023, the agencies also issued a joint document on the use of predetermined change control plans (PCCPs) to manage certain device changes where regulatory authorization before marketing is typically required. The medical device industry and regulatory bodies recognize PCCPs as a means to manage risks in a timely, ongoing fashion through monitoring, maintenance, and/or improving device performance.

Companies also are developing their own AI training models incorporating ethics, transparency, and accountability.

Myth: AI-enabled devices introduce the potential for fake results in important patient scans.

Fact: AI in medical devices does not look or operate anything like the AI chat-bots or other "unlocked" AI algorithms that have received media attention. The type of AI attracting attention for inaccurate or faked content is "generative AI," which generates new content from data without repeating the data. For example, generative AI can be used to produce a piece of art that might resemble classic art but is brand new.

Most AI-enabled devices were cleared or approved with "locked" algorithms. This means that once the FDA has authorized the marketing of the device, it cannot be modified without FDA review and authorization. If a device manufacturer intends to modify the algorithm (e.g., based on real-life use and/or new data), the FDA would need to review and authorize the modified algorithm before it could be marketed. To date, FDA has not authorized any device that uses generative AI or artificial general intelligence (AGI) or is powered by large language models.

Myth: AI will replace doctors, nurses, radiographers, and other highly trained practitioners.

Fact: AI will not replace people. AI-enabled technology is a tool to support clinicians and improve patient care, like any other piece of technology in a medical toolkit. The technology already is enabling better understanding of diseases and faster, accurate results, helping doctors diagnose injury and illness and propose appropriate treatment. Clinicians determine their practice of medicine. They decide whether to use AI-enabled technology, as with any medical device.

AI also is being used to help make the delivery of healthcare more efficient and accessible. For example, AI-enabled software is used in some hospitals to optimize the efficient scheduling of operating rooms. Technology enabling clinicians to see more patients in less time with fast, accurate results helps patients and the entire health care system. AI could mean less time for patients in a waiting room.

The current most frequent use of AI in radiology is important because more than 80 percent of all health system visits include an imaging exam, most commonly an X-ray. AI-enabled X-rays, for example, can promote high quality services and expand healthcare access for rural and underserved populations.

Similarly, AI-based platforms can help clinicians "seeking tools that can address issues related to access, burnout, variability, equity, and cost in breast imaging to elevate and enhance the detection and diagnosis of breast cancer."

Researchers are using AI to gain insights into diseases, with the goal of improving diagnoses and treatment. For example, a recent deep learning study identified patterns and processes to help researchers better understand how chronic obstructive pulmonary disease causes inflammation.

Congressional hearing witnesses agreed AI could reduce administrative tasks, freeing up physician time and potentially easing physician shortages, especially helpful in rural and underserved areas.

Myth: AI will benefit only well-funded, elite hospitals and medical practices.

Fact: AI can facilitate and promote access to health care in rural and other underserved communities. The technology is enabling better accuracy of equipment that innovators simultaneously are making lightweight and flexible such as magnetic resonance imaging devices and multiple clinical applications in a single platform. These innovations make critical technology more accessible to more health care facilities.

Myth: AI-enabled devices will perpetuate bias, harming patients.

Fact: When considering "bias" in AI/ML-enabled medical devices, it's important to recognize that not all bias is "bad bias." In some cases, algorithms may be developed with deliberate bias to optimize the device for the intended population (e.g., devices intended for a geriatric population).

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FDA's review of AI/ML algorithms in devices includes an assessment to ensure unwanted bias is adequately mitigated. The technology relies on data sets to build, train, and tune algorithms. Large datasets facilitate robust algorithm development and can help identify and mitigate unwanted bias. For example, AI could interpret data to help practitioners understand physiological, natural bias, such as stroke and heart attack symptoms presenting differently in men and women, and reduce technology-related errors, such as device limitations over darker skin tones.

Terms, Defined:

The medical device industry, developers of consensus standards, and regulators are working to develop standardized terms and definitions. These definitions are verbatim from current FDA resources:

Artificial Intelligence has been broadly defined as the science and engineering of making intelligent machines, especially intelligent computer programs (McCarthy, 2007). Artificial intelligence can use different techniques, including models based on statistical analysis of data, expert systems that primarily rely on if-then statements, and machine learning.

Machine Learning is an artificial intelligence technique that can be used to design and train software algorithms to learn from and act on data. Software developers can use machine learning to create an algorithm that is 'locked' so that its function does not change, or 'adaptive' so its behavior can change over time based on new data.

Some real-world examples of artificial intelligence and machine learning technologies include:

- An imaging system that uses algorithms to give diagnostic information for skin cancer in patients.
- A smart sensor device that estimates the probability of a heart attack.

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