News and Perspectives

Despite Rapid Adoption, We Don't Know If Most AI Devices Improve Patient Outcomes

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Abstract

As the speed of adoption in health care increases, validation of AI medical devices lags behind—leaving uncertainty about whether these tools will ultimately benefit patients. In this *News and Perspectives* article, JMIR Correspondent Simon Spichak reports on this evidence gap and the complexities, frustrations, and risks around it.

Key Takeaways:

- Although the Food and Drug Administration has greenlit over 1600 AI-enabled medical devices for marketing, few of their developers collected evidence to assess whether these devices impact patient outcomes.
- The speed of adoption is frustrating to researchers who have worked on medical devices for years to satisfy safety and efficacy standards for administrators, as they now see riskier devices being adopted faster.
- There is discordance between clinicians and marginalized individuals on what health outcomes are most important.

As of October 2026, there are 1614 AI devices greenlit by the US Food and Drug Administration (FDA). Almost none have data on whether they improve patient outcomes. A study published in *PLoS One* earlier this year found that only 3 of 1357 AI devices that were authorized at the time of the study's publication assessed any patient outcomes. Many other AI tools commonly used in health care, including some ambient scribes and medical chatbots, don't necessarily require regulatory approval.

Researchers like Maxim Topaz, PhD, RN, associate professor of nursing at Columbia University, have spent years carefully developing machine learning algorithms for implementation in health settings and are now seeing devices with riskier generative AI components and less data to support them being implemented across the board.

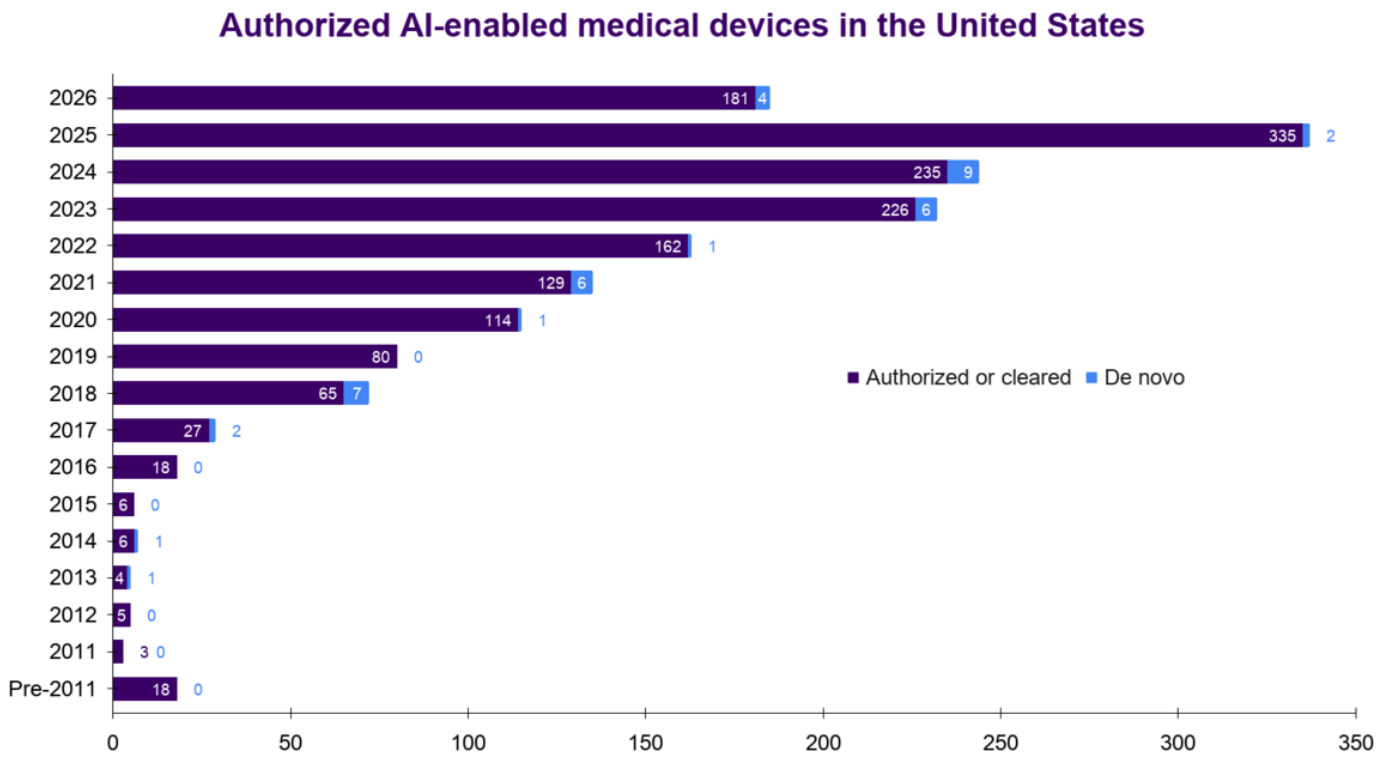
"We were grilled on previous generations of this technology," Topaz says. "It wasn't [anywhere] near in terms of safety risks to this technology that's rolling out right now."

But growing burdens within the health care system, coupled with the speed of AI development and a lack of regulatory standards to ensure these devices are beneficial, are creating a concerning evidence gap for AI-enabled medical devices and tools. Discordance on the outcome measures that matter among researchers and individuals accessing the health care system contribute to the complexity of the challenge.

The Problem

Companies with AI devices may access the US market through the FDA's 510(k) clearance pathway by proving their device is noninferior to similar existing products. When there are no equivalent devices, companies must go through the more arduous de novo pathway, which requires establishing safety and effectiveness.

Before 2020, there were 232 AI-enabled devices, of which 11 had received de novo authorization. Then, 2020 was a milestone year, with over 100 devices greenlit, though only one through the de novo pathway. The number of total devices approved or cleared grew each year, with the vast majority cleared rather than going through the de novo pathway.



Graph accurate as of October 30, 2026.

"Most of the AI that impacts health outcomes [is] outside the purview of the FDA," says Leo Anthony Celi, MD, MPH, the senior Massachusetts Institute of Technology scientist who led the study. Many health care systems have already adopted AI scribes and chatbots, while people regularly use chatbots for health advice. "We thought that starting with that is a good narrow focus to [better] alert the community and the world that we might be doing this [deployment of AI] all wrong."

Why Has AI Adoption Increased?

The availability of AI tools has turned the process of bringing new devices to market from slow and deliberate into a race—shining a spotlight onto systemic gaps.

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>
> Leo Anthony Celi, MD, MPH

Since 2020, Topaz and his colleagues have been developing the Homecare-CONCERN algorithm to predict which home health care patients are at risk of unplanned hospitalization or an emergency visit within the next 60 days. The project will run through 2031 before they know whether the algorithm improves outcomes.

"Home health care is somewhat an orphan child in terms of technology development," he says. "Most risk scores sold to home care agencies between now and then will skip this step, and I have no good argument for why the market should wait for us," he wrote on LinkedIn.

With many clinicians and administrators overburdened by electronic health records and other paperwork, AI devices present an appealing solution for administrators, who Topaz says are pressured to use these tools before any evidence that they're effective, safe, and improve patient outcomes.

"We've never had a technology that evolves this rapidly, and now I think the gift of AI is [in] making us appreciate how broken our systems are," says Celi.

What Outcomes Matter?

Experts say that the FDA isn't adequately designed to assess these devices for their impact on patient outcomes. The agency is also seeking input from industry and other stakeholders to decide how to regulate generative AI devices in the future.

"It's the floor, it's not the ceiling," says Celi. "What matters more is what happens after the FDA approval and very few organizations, I think, are structured in a way that can provide this continuous monitoring of AI devices as they pertain to population health."

AI has also upended the research publishing industry. Even when patient outcomes are measured, by the time a trial goes from ideation to execution and publication, the underlying AI technology it was based on becomes obsolete.

Further complicating the issue, there can be discordance between the outcomes that researchers and doctors believe are important, and those that patients—especially those from marginalized communities—believe matter. “Global health is shaped by the [World Health Organization]; the engagement of those who are most affected by global health problems are seldom surfaced,” says Celi. He believes that a lot of the current patient engagement conducted by people developing these AI tools is “performative.”

A 2017 systematic review identified that doctors often prioritize the structure—the health care environment and resources offered to patients—while patients place more importance on the process by which interventions are delivered. Another study found that physicians tend to underestimate patients’ pain and overestimate their level of education, understanding, confidence, and trust.

AI is already changing health care, but is it making it better for patients? It’s up to regulators—as well as the research and medical device community—to liaise with individuals navigating the system to figure out how to evaluate the risks and benefits of these tools without completely stalling deployment speed.

“I won’t pretend that I have all the answers because I don’t,” says Celi. “The only way I feel that I get closer to the answers is by continuously having conversations with those who are or who have been marginalized by health care.”

Keywords: artificial intelligence; medical devices; United States Food and Drug Administration; technology assessment, biomedical; patient outcome assessment; evidence-based medicine; health care quality, access, and evaluation; government regulation

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