Bringing AI Applications to Patients Faster

A new study asked technology leaders how systems can be streamlined.

Artificial intelligence (AI) has tremendous potential to improve medicine, but so far, translating these technologies from the drawing board to patient bedsides has been slow and laborious. To better understand why, researchers at the University of Miami Miller School of Medicine, technology innovation firm Covered By Group and Weill Cornell Medicine interviewed a small group of digital health and health care AI founders and executives to get their insights into how current systems could be improved. The results were published in the Journal of Medical Internet Research.

Azizi Seixas, Ph.D.

“While some AI technologies have made it into the clinic, most of these have come from large conglomerates, like Google or Amazon,” said Azizi Seixas, Ph.D., interim chair of the Department of Informatics and Health Data Science and senior author on the study. “Early-stage startup companies, which produce much of the innovation, are hardly in the mix, and we wanted to understand the barriers they face and how we might help overcome them.”

AI is already revolutionizing research, revealing protein structures that were once thought impossible to predict. In hospitals, these technologies could detect patterns human
clinicians might miss, such as identifying early-stage cancer on a scan or harnessing a confluence of vital signs to predict an ICU patient might code in 30 minutes.

**Integrating Digital Health, AI into Clinical Practice**

To understand why AI is moving so gradually into the clinic, the researchers organized a focus group of early-stage digital health and health care experts, including venture capitalists, founders and CEOs. Their responses showed that hospital systems and tech startups are divided into two distinct cultures: abundant caution on one side (first, do no harm) and an urgent drive to disseminate new technologies on the other. The two communities share goals but often lack a common language to accomplish them.

One of the main issues facing startups is the diverse procurement approaches they find in different hospital systems. There is no single protocol; rather, companies must learn to navigate each system individually.

“Health care system procurement processes are extremely fragmented,” said Iredia Olaye, Ph.D., CEO of Covered By Group, researcher at Weill Cornell Medicine and first author on the study. “As a result, early-stage companies have more significant barriers to integrating digital health and AI into clinical practice than their later-stage technology conglomerate counterparts. The funding and regulatory processes and lack of knowledge digital health executives and health care providers bring to the process are barriers to successful integration.”
In some cases, companies have abandoned going after major health systems to market their products directly to employers or consumers.

“The problem with this approach is that, for truly integrated patient care, physicians and other clinical staff must lead the charge,” said Dr. Olaye. “For digital health and AI use at home, consumers would benefit from physicians' insights on which technologies will help them the most.”

**Challenges in Regulatory Approval Process**

Another barrier is the cost of conducting randomized clinical trials. Startups face a Catch-22: If they conduct trials, they may never recoup the costs; if they don’t do trials, they will never gain regulatory approval.

On a public policy level, the authors would like the Food and Drug Administration (FDA), and other agencies in the U.S. and abroad, to review their guidelines to better support these innovative technologies. The FDA’s 510(k) clearance, which governs devices that are substantially similar to existing technologies, was created 10 years ago, long before many AI and digital technologies emerged.

“It’s just not consistent,” said Dr. Seixas. “We need the FDA to update their process to better differentiate between AI, digital health and medical devices and provide clearer guidelines for companies and health systems.”

The Miller School of Medicine, through the Department of Informatics and Health Data Science and other groups, is finding ways to accelerate AI’s transition into clinical care. Most startup health technology companies don’t have chief
scientific or chief medical officers, making it challenging to organize clinical research. Academic institutions like the Miller School can help provide that expertise to enable clinical studies and facilitate FDA approval.

“Tech came into health care thinking they were going to change how we do things, but many of them failed because they're just not wired to care for patients,” said Dr. Seixas. “But that is exactly our wheelhouse. To move forward, we need to add an innovation and technology infrastructure to better incorporate and implement these solutions into health care.”

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