Physician-scientist and AMA member Michael Abramoff, MD, PhD, identified a problem and then painstakingly spent eight years building an augmented intelligence (AI) solution to fix it.

The Food and Drug Administration (FDA) and a quartet of venture capital firms say he forged a path that others seeking to develop health care AI systems can follow.

A professor of ophthalmology at the University of Iowa's Carver College of Medicine, Dr. Abramoff was disturbed by how long it often takes for patients with diabetes to see an eye-care specialist for a diabetic retinopathy exam. And he was bothered by how specialists' schedules are frequently crammed full of routine eye-exam visits that did not require their level of expertise.

“Clearly, the standard practice is not working, and people are not getting the exams they need,” Dr. Abramoff said, citing various studies finding that between 15% and 50% of patients who need a diabetic retinopathy exam are getting one.

A diabetic retinopathy screening by a specialist costs $220. A screening using Dr. Abramoff’s system, called IDx-DR, costs $30 to $50.

“I measure success by making patients’ lives better. That’s what this is about—making it easier to get the diagnosis and the therapies they need at lower cost,” he said.

The AMA believes AI, often referred to as “artificial intelligence” in popular culture, should enhance human intelligence rather than replace it.

Dr. Abramoff agreed.

“You had a phase where some said AI will replace doctors entirely,” he said. “We’re in a more realistic phase now, where we realize these systems are not perfect and have to fit into a larger system.”
Overnight success takes 8 years

Dr. Abramoff arrived at the University of Iowa in 2002 and founded his company, IDx, in 2010. Then began a long, twisting journey, which rapidly accelerated in 2018:

- The FDA gave IDx-DR status as a “breakthrough device” that February meritng expedited review.
- FDA authorizes IDx-DR that April to go on the market.
- University of Iowa Health Care starts using IDx-DR that June.
- Results of a 900-patient, 10-site clinical trial showing the effectiveness of the IDx-DR system were published in *Nature Digital Medicine*.
- Four venture capital firms invest a combined $33 million in the company.

The key to the success was rigorous design and validation testing of the system where it would be used—in primary care offices with all kinds of patients, Dr. Abramoff said.

Additionally, care was taken to ensure that using IDx-DR did not cause workflow interruptions and that it could be integrated into a primary care practice’s electronic health record.

“It’s relatively simple with two messages: One for the order, and one for the results,” Dr. Abramoff explained. “If a result is abnormal, you can generate an automatic appointment with an eye-care specialist.”

He added that clinical guidelines and standards developed by specialists are used to set the level of diabetic retinopathy that triggers a referral.

Clinically inspired AI spurs investment

The investment funding was led by San Francisco-based 8VC, whose founding partner Drew Oetting said IDx’s “clinically inspired AI” distanced the company from the pack of health care startups hyping their use of AI.

“Some of the biggest companies in the world are trying to implement AI in health care, but IDx is leading the way in real-world execution,” Oetting said in a statement.
Using IDx-DR and other AI diagnostic systems will soon fit easier into practices’ billing systems. The AMA Current Procedural Terminology (CPT®) editorial panel accepted a new CPT code for automated point-of-care retinal imaging.

There are about 20 organizations using IDx-DR. Next in the pipeline are diagnostic tools for glaucoma, macular degeneration and diseases unrelated to the eye, Dr. Abramoff said. He added that other companies with AI-driven diagnostic tools for cervical cancer and skin diseases are following the template the FDA developed for approving IDx-DR.

Learn more with the CME module, “Artificial and Augmented Intelligence in Health Care: 2018-2019 edition of Health Care Trends,” which is enduring material and designated by the AMA for a maximum of 1.0 AMA PRA Category 1 Credit™.

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