April 30, 2021

WHAT YOU NEED TO KNOW ABOUT

New Applications of Artificial Intelligence Software in Health Care

PRO POINTS

- **Venture capital investments in health care-**focused artificial intelligence and machine learning companies are surging. Rock Health reports a 96 percent increase in funding to AI companies marketing to health care providers between 2019 and 2020.

- **Health systems are buying software to mine** electronic health records and then flag the highest-risk patients or identify broader population health trends. Federal rules mandating easier data sharing — both directly to patients and between providers and third-party apps — will free up large volumes of health data for advanced analysis by AI.

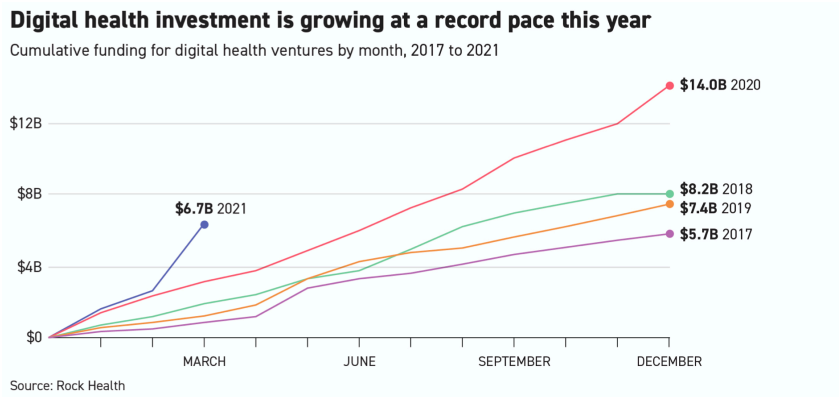
- **Patient advocates warn that black-box algorithms** could increase disparities.

- **The Food and Drug Administration is working on** setting up parameters for artificial intelligence in health care, and lawmakers have called for more transparency from companies selling the technology.

HOW WE GOT HERE

AI systems that can visually interpret patients' diagnostic scans have seen particular uptake in imaging-heavy specialties such as radiology and dermatology, though patient advocates have warned that the incomplete and biased data sets often used to train the technology leave darker- skinned patients at higher risk for diagnostic errors.

Experts say AI's impact on the pandemic response has been minimal. Health systems such as Stanford's are experimenting with technology to triage the highest-risk Covid-19 patients, but it hasn't meaningfully influenced Covid-19 diagnoses. Some researchers have used the technology to narrow down the types of drugs to investigate as potential Covid-19 treatments.



WHAT'S NEXT

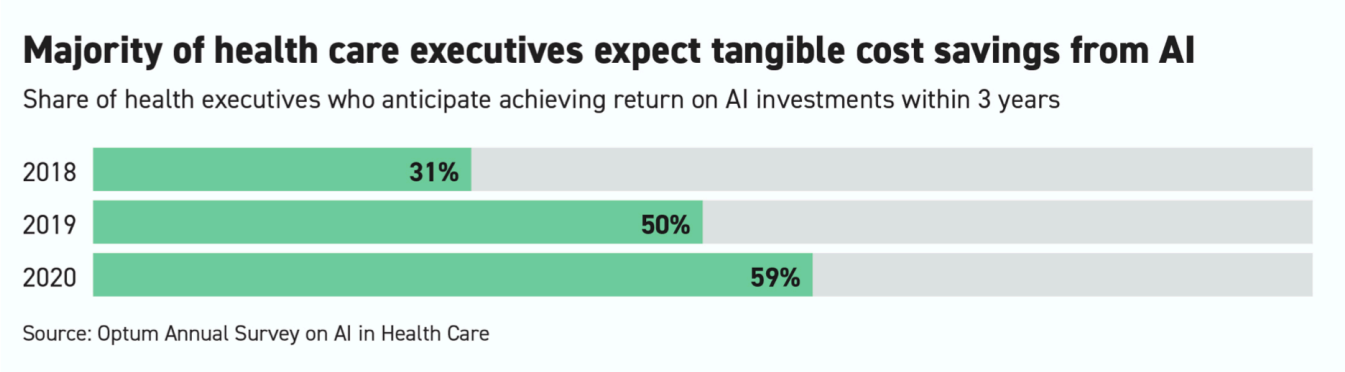
Regulators and lawmakers are evaluating the costs and benefits of artificial intelligence in health care. The FDA is working on a regulatory framework for artificial intelligence in health care through its Software as a Medical Device division, and officials have said the framework may evolve. Among the agency's goals: developing "good machine learning practices to evaluate and improve machine learning algorithms."

But patient advocates are sounding the alarm about the potential for faulty algorithms and skewed data sets to exacerbate historic racial and demographic health disparities. One algorithm used by UnitedHealthcare' s Optum was designed to flag the patients in greatest need for follow-up care based on an estimate of past health care costs. But the system did not account for historic barriers to care for Black patients,

and recommended white patients with similar health conditions more frequently than Black patients.

As health systems and insurers increasingly explore artificial intelligence as a means for directing limited resources to patients in the most need, the Agency for Healthcare Research and Quality is examining algorithms' potential to exacerbate racial and demographic disparities.

Lawmakers are beginning to examine AI's role in health care but haven't cemented a comprehensive strategy. A letter from Sens. Elizabeth Warren , Ron Wyden and Cory Booker and Rep. Barbara Lee questioning the use of race-based algorithms in health care last year prompted AHRQ's inquiry. Booker, Wyden and Rep. Yvette Clarke also introduced a measure in 2019 that would authorize the Federal Trade Commission to require companies to closely assess highly sensitive algorithmic systems.



POWER PLAYERS

- **The Centers for Medicare and Medicaid Services, and Biden's nominee Chiquita Brooks-LaSure:** CMS recently began reimbursing physicians to use certain imaging algorithms. If confirmed as CMS administrator, Brooks-LaSure would be positioned to expand the agency's AI coverage.

- **Bakul Patel:** As director of the Food and Drug Administration's Digital Health Center of Excellence, Patel is in charge of shaping the agency's approach to regulating artificial intelligence. That may include incorporating real-world evidence — data gathered from patients' experience outside clinical trials — into the evaluation of AI.

- **The Agency for Healthcare Research and Quality, and acting director David Meyers:** AHRQ is leading a major investigation into algorithms' potential to exacerbate racial and demographic disparities.

- **Micky Tripathi:** As HHS' national coordinator for health IT, Tripathi is in charge of implementing sweeping federal rules mandating seamless data sharing between providers, payers and patients. As more organizations adopt common data standards to ease data flow, more data can flow into third- party apps and software guided by artificial intelligence.