FDA Approves App That Diagnoses Autism in Children Earlier

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Black children, girls, and children from disadvantaged backgrounds are more likely to receive a late autism diagnosis. But a new app authorized by the Food and Drug Administration (FDA) may soon change that by helping primary care doctors identify the developmental disability in very young children, Fierce Biotech reports.

The Canvas Dx app was designed by Cognoa for children between 18 months and 5 years old—the age range during which interventions may have the greatest effect on neurodevelopment, according to autism experts. The app uses answers to questionnaires completed by a child's parent or caregiver as well as data provided by doctors and reviews a video of a child performing tasks or interacting with others to help make an assessment in a doctor's office or remotely.

The app uses machine learning to help doctors make earlier, more accurate determinations of autism. (The traditional diagnosis process can necessitate specialist referrals and can take years to complete.)

In a clinical trial involving 425 children 18 months to 6 years old, Canvas Dx confirmed the diagnoses made by a panel of specialists 81% of the time for kids who tested positive for autism and 98% of the time for those who tested negative.

"The current system is already at a breaking point, as it is unable to provide early diagnoses and intervention opportunities to many children and families," said Dave Happel, Cognoa's CEO. He added that the app would allow all children with autism to get diagnosed regardless of their gender, race or ethnicity.

"Autism spectrum disorder can delay a child's physical, cognitive and social development, including motor skill development, learning, communication and interacting with others," said Jeff Shuren, MD, the director of the FDA's device center. "The earlier [autism spectrum disorder] can be diagnosed, the more quickly intervention strategies and appropriate therapies can begin."

Autism affects about 1 in 54 children in the United States. Signs can become noticeable in children at age 18 months, but the average age of diagnosis is 4 1/2 years old.

To learn more about the signs and effects of autism on kids of color, check out "Understanding Autism and Impact on African American Children."

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