AI expert calls for end to UK use of ‘racially biased’ algorithms

Gender bias in AI: building fairer algorithms

Bias in AI: A problem recognized but still unresolved

Machines Taught by Photos Learn a Sexist View of Women

Millions of black people affected by racial bias in health-care algorithms

When It Comes to Gorillas, Google Photos Remains Blind


The Best Algorithms Struggle to Recognize Black Faces Equally

Facebook’s ad-serving algorithm discriminates by gender and race

Califonia investigating racial bias in healthcare algorithms

Artificial Intelligence has a gender bias problem – just ask Siri

‘The Computer Got It Wrong’: How Facial Recognition Led To False Arrest Of Black Man
Equitable Artificial Intelligence in Healthcare

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Disclosures
I am an employee of Cognoa and hold Cognoa stock options. I am an employee of the Pediatric Subspecialty faculty which is a foundation with CHOC. I am an employee of Chapman University. I receive consulting fees for Cognito Therapeutics. I am a paid advisor for MI10 LLC. I am a co-founder and own stock for NTX, Inc. I am an advisor for HandzIn and have vested stock. I am a volunteer board member of the AAP - OC chapter and AAP – California.
AI can make the visible invisible and make the invisible visible.

-Anthony Chang, MD, MBA, MPH, MS
Socially Responsive AI for Equitable Outcomes

- Equitable
  - Race/Ethnicity
  - Gender
  - Age
  - Developmental Condition

- Interpretable

- Can be tuned to prevalence in target population

- Can be tuned to cultural norms in target locale
1. Be aware of contexts in which AI can help correct for bias and those in which there is high risk for AI to exacerbate bias.

2. Establish processes and practices to test for and mitigate bias in AI systems.

3. Engage in fact-based conversations about potential biases in human decisions.

4. Fully explore how humans and machines can best work together.

5. Invest more in bias research, make more data available for research (while respecting privacy), and adopt a multidisciplinary approach.

6. Invest more in diversifying the AI field itself.
Racial, Ethnic, and Sociodemographic Disparities in Diagnosis of Children with Autism Spectrum Disorder

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ABSTRACT: This special article uses a biosocial-ecological framework to discuss findings in the literature on racial, ethnic, and sociodemographic diagnostic disparities in autism spectrum disorder. We draw explanations from this framework on the complex and cumulative influences of social injustices across interpersonal and systemic levels.

Inequities & Inefficiencies

**VAST OPPORTUNITIES TO IMPROVE OUTCOMES**

- Waiting lists of up to 18 months
- Parents visit 4–5 clinicians on diagnostic journey
- 2/3 of toddlers flagged for autism are NOT referred to specialists
- 85% of children identified with ASD had concerns noted in their records by age 3
- Girls are diagnosed with autism 1.5 years later, on average, than boys
- 40% of children were not evaluated for ASD within the early intervention window
- 1 of 4 children under age 8 with ASD – most of them African American or Hispanic – are not being diagnosed

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1. Begeer, Bouk, Boussaid, Terwogt, & Koot, 2009
2. Goin-Kochel, Mackintosh, & Myers, 2006
3. Centers for Disease Control and Prevention.
5. McCormick et al., 2020
6. Baio, Wiggins, Christensen et al., 2018
Canvas Dx is the first FDA-authorized Software as a Medical Device that aids healthcare providers to diagnose or rule out autism in young children. Canvas Dx harnesses clinically validated artificial intelligence technology to aid providers in diagnosing ASD in children between the ages of 18 and 72 months who are at risk of developmental delay.

*Canvas Dx is manufactured by Cognoa Inc.,

Using Multiple Sources To Prevent Bias

Canvas Dx is designed to abstain when presented with insufficient inputs. This is an important safety mechanism to reduce the risk of false classifications.
Canvas Dx Pivotal Study

Multi-site, Prospective, Blinded, Method-comparison Cohort Study

Objective
To compare the diagnostic output of the device (with algorithm V1) to the clinical reference standard, consisting of diagnosis made by a care specialist based on DSM-5 criteria and validated by one or more reviewing care specialists

Study Endpoints

- **Primary Endpoints**
  - Positive predictive value (PPV)
  - Negative predictive value (NPV)
  - Measurement of the proportion of all children for whom the device provides an indeterminate output

- **Secondary Endpoints**
  - Sensitivity and specificity

Study Details

- N=425 completed subjects
- 18-72 months with concern for developmental delay
- 14 sites
- Study population mirrored US population across race, ethnicity, socioeconomic status

Pivotal Study Completers vs U.S. Census

- Study participants broadly representative of the U.S. population in terms of race, ethnicity, and socioeconomic background.

The sample population had a higher level of parental education and a lower household income relative to the most recent U.S. census data estimates.

“There was no evidence of device performance inconsistency across subjects’ sex, race/ethnicity, household income, parental education level, or geographic location. This is a promising initial finding given ongoing concerns about gender, racial and geographic biases in traditional ASD diagnostic processes.” *
FDA Authorizes Marketing of Diagnostic Aid for Autism Spectrum Disorder

Today, the U.S. Food and Drug Administration authorized marketing of a device to help diagnose autism spectrum disorder (ASD). The Cognoa ASD Diagnosis Aid is a machine learning-based software intended to help health care providers diagnose ASD in children 18 months through 5 years of age who exhibit potential symptoms of the disorder.

“Autism spectrum disorder can delay a child’s physical, cognitive and social development, including motor skill development, learning, communication and interacting with others. The earlier ASD can be diagnosed, the more quickly intervention strategies and appropriate therapies can begin,” said Jeff Shuren, M.D., J.D., director of the FDA’s Center for Devices and Radiological Health. “Today’s marketing authorization provides a new tool for helping diagnose children with ASD.”

The Centers for Disease Control and Prevention defines ASD as a “developmental disability that can cause significant social, communication and behavioral challenges” and is estimated to affect about 1 in 54 children. Because ASD symptoms can vary greatly, the disorder may be difficult to diagnose. While ASD may be detected as early as 18 months old, many children are not diagnosed until later in childhood, which can delay treatment and early intervention. The average age of diagnosis for ASD is 4.3 years. Some delays in diagnosis are due to the need for children to be referred to specialists with expertise in ASD.

Current Canvas Dx performance metrics (with algorithm V2)

- **NPV**: 98%
- **PPV**: 82%
- **FDA min requirement**: 94%
- **Determinate Rate**

Sensitivity 85% & Specificity 96%; respectively in those with determinate results.
Canvas Dx is a Software as a Medical Device (SaMD) That Aids Physicians in Diagnosing Autism Spectrum Disorder (ASD) in Young Children

Canvas Dx harnesses clinically validated artificial intelligence (AI) technology to aid physicians in diagnosing ASD in children between the ages of 18 and 72 months who are at risk of developmental delay.

It received Breakthrough Device designation from the FDA in October 2018 and was granted De Novo marketing authorization in June 2021.1,2

Indications for Use
Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of autism spectrum disorder (ASD) for patients ages 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider.

The device is not intended for use as a stand-alone diagnostic device but as an adjunct to the diagnostic process. The device is for prescription use only (Rx only).

Contraindications
There are no contraindications to using Canvas Dx.

Precautions, Warnings
The Device is intended for use by healthcare professionals trained and qualified to interpret the results of a behavioral assessment examination and to diagnose ASD.

Important Information

Precautions, Warnings

The Device is intended for use in conjunction with patient history, clinical observations, and other clinical evidence the HCP determines are necessary before making clinical decisions. For instance, additional standardized testing may be sought to confirm the Device output, especially when the Device result is not Positive or Negative for ASD.

Canvas Dx is intended for patients with caregivers who have functional English capability (8th grade reading level or above) and have access to a compatible smartphone with an internet connection in the home environment.

The Device may give unreliable results if used in patients with other conditions that would have excluded them from the clinical study.

Among those conditions are the following:

- Suspected auditory or visual hallucinations or with prior diagnosis of childhood onset schizophrenia
- Known deafness or blindness
- Known physical impairment affecting their ability to use their hands
- Major dysmorphic features or prenatal exposure to teratogens such as fetal alcohol syndrome
- History or diagnosis of genetic conditions (such as Rett syndrome or Fragile X)
- Microcephaly
- History or prior diagnosis of epilepsy or seizures
- History of or suspected neglect
- History of brain defect injury or insult requiring interventions such as surgery or chronic medication

The Device evaluation should be completed within 60 days of the time it is prescribed because neurodevelopmental milestones change rapidly in the indicated age group.
In Conclusion ..... 
Artificial Intelligence has potential to either perpetuate or address bias and inequity in healthcare

Bias can be reduced by awareness of context, use of demographically representative data & deliberate application of processes to test for and mitigate bias. Investment in bias research, and efforts to diversify the field of AI itself, are also needed.