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Milestone Population Health Measure Clarification from NCQA Expands Sight-Saving Access to Early Diagnosis of Diabetic Retinopathy and Macular Edema Through Autonomous AI

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(Coralville, Iowa) July 7, 2020 – Blindness due to diabetic retinopathy and macular edema is largely preventable with early diagnosis. Today the National Committee for Quality Assurance (NCQA) made expanded access to early diagnosis more achievable. It issued a clarification to its Healthcare Effectiveness Data and Information Set (HEDIS) measures confirming the approved use of autonomous AI, as delivered by the IDx-DR platform, to diagnose diabetic retinopathy and macular edema. Hospitals will now be able to confidently use the IDx-DR system to unlock the financial incentives related to compliance with HEDIS measures, and to address gaps in care in at-risk populations.

IDx-DR is an autonomous AI system that provides instantaneous, point-of-care diagnostic assessment for diabetic retinopathy and macular edema without physician review of the diagnostic decision.

“The potential for autonomous AI to improve access, heighten quality, and lower cost for patients is tremendous. Today’s announcement is a key milestone in the acceptance of autonomous AI in a healthcare setting,” observed Michael Abramoff, MD, PhD, Founder and Executive Chairman of Digital Diagnostics. “Now, a hospital can leverage AI, rather than their limited specialist physician resources, to diagnose this common illness.”

Early Diagnosis: Preventing Blindness in At-Risk Populations

Expanding the use of autonomous AI in healthcare expands healthcare access in underserved communities and lowers the cost of care for all. Further, it allows specialized physicians to practice "top of license," reducing the amount of time they spend on routine tasks and enabling better triage of patients that need specialty care.

Preventing blindness is at the heart of both the IDx-DR system and the NCQA clarification; earlier diagnosis of more cases means more patients with diabetic retinopathy can keep their vision. More than 30 million Americans have diabetes, and an estimated 60,000 lose vision each year from diabetic retinopathy, a number that is heavily skewed towards minorities. If caught in its early stages, vision loss and blindness are almost entirely preventable, yet less than half of people with diabetes get regular eye exams. By incentivizing frontline healthcare providers to administer a diabetic retinopathy exam during a routine office visit, IDx-DR increases patient access to this potentially sight-saving exam.

How does IDx-DR work?

Digital Diagnostics, a pioneering AI diagnostics company founded by ophthalmologist and computer scientist Dr. Michael Abramoff, developed IDx-DR, the first autonomous AI system ever to receive FDA authorization. The system diagnoses diabetic retinopathy and diabetic macular edema in a primary care setting without physician involvement in the diagnosis. It allows patients to avoid an additional visit to a specialist, which would require another trip to another doctor, another co-pay, and for some patients, a long wait for an appointment.

IDx-DR Regulatory Timeline

Digital Diagnostics has worked in concert with patient and physician organizations as well as Federal agencies at every step of its journey toward expanding access to early diagnosis:

- Feb. 2018: IDx-DR receives "Breakthrough Device" designation from the FDA
- Apr. 2018: First time FDA authorizes an autonomous AI, IDx-DR, in any field of medicine, to be safe, efficient, and equitable.
- June 2018: Introduction of a temporary bridge coding I CPT® code 92250-TC for autonomous AI for diagnosing diabetic retinopathy and diabetic macular edema
- May 2019: AMA's CPT® Editorial Panel creates for the first time a CPT® category I code 9225X for autonomous AI, which makes a clinical decision without specialist review, to go into effect Jan 1, 2021
- Dec. 2019: American Diabetes Association updates its Standard of Diabetes Care to include autonomous AI for diabetic retinopathy.
- July 6, 2020: NCQA updates HEDIS measure language for comprehensive diabetes care to include autonomous AI.

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About Digital Diagnostics

Digital Diagnostics is a pioneering AI diagnostics company on a mission to transform the quality, accessibility and affordability of healthcare. Founded and led by Dr. Michael Abramoff, an ophthalmologist, neuroscientist and computer engineer, Digital Diagnostics developed a patented biomarker-based approach to build autonomous algorithms that make clinical decisions without human intervention. Digital Diagnostics and its flagship product IDx-DR, an autonomous AI system FDA-approved to diagnose diabetic retinopathy and diabetic macular edema, has proven that intelligent diagnostic platforms can be used safely, efficiently and equitably to improve patient outcomes. As it expands into other diagnostic capabilities, Digital Diagnostics has paved the way for automated diagnosis to become a new standard of care that will contribute significantly to democratizing healthcare.

*About NCQA HEDIS Measures

The Healthcare Effectiveness Data and Information Set (HEDIS) is one of health care's most widely used performance improvement tools; it is a system administered by the National Committee for Quality Assurance (NCQA). Approximately 191 million people are enrolled in plans that report HEDIS results. HEDIS' 90 performance standards range across six domains of care: effectiveness, access and experience of care, utilization, health plan information, and measures collected from electronic clinical data systems. Studies show health plans that meet HEDIS standards are associated with lower health care costs. Analysis of HEDIS data is also used to identify gaps in care and use of preventive care in people with chronic diseases such as diabetes, heart or lung disease and other costly conditions.

For more information, visit https://www.ncqa.org/hedis/.
The measures announced on July 6, 2020 are summarized here.

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