Setting Standards for Clinic-based Digital Cognitive Assessments

Recommendations from the Global CEO Initiative on Alzheimer's Disease

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AGREEDementia Workgroup Meeting
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GLOBAL CEOINITIATIVE
–ON ALZHEIMER'S DISEASE–

Disclosures

Louisa I. Thompson, Barak Gaster, Dustin B. Hammers, A. M. Barrett, and Christopher R. Butler report no conflicts of interest.

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Workgroup Core Team Members



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Workgroup Progress

2024

2025

APR

Defined Unique Benefits of DCAs

MAY

Described Contexts of Use of Focus

JUNE

Aligned on Test Characteristics

SEPT

Develop and Detail TPPs for Each Context of Use

OCT

Presentation at Lausanne XI/ CTAD Symposia

APR

Presentation at AD/PD Conference

JAN - MAY

Publication Development for Journal Submission

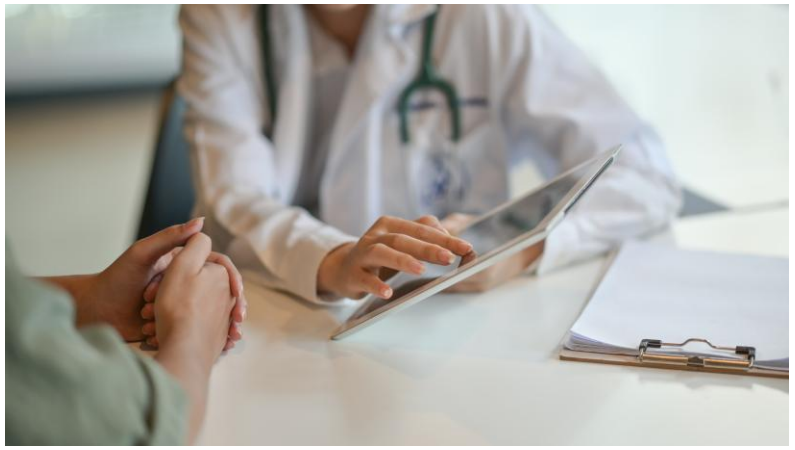


DCA Workgroup Objective

Overarching Goal

- Prepare for the **adoption of digital cognitive assessments in clinical care** so patients experience a more simple, timely, and accurate diagnostic experience, **starting with the US**

- Our objective was *not* to validate or comparatively evaluate individual tests, but to rapidly develop an environment for efficient and effective utilization, that is scientifically-based and patient-focused



Background



- Majority of ADRD cases in the US still go undetected and undiagnosed. Estimates suggest only about 10% of individuals with MCI receive a diagnosis.
- Only about a third of older adults 65 years of age or older report having been asked about memory concerns or had cognitive screening.
- Until recently, specific guidance on how and when to conduct cognitive screening has been limited.

Potential Benefits of Early Screening and Diagnosis:

- Identify and address treatable causes and modifiable risk factors, offer disease education, and develop a plan.
- Facilitate access to approved therapies, clinical trials, and other care and support, including new U.S. Medicare GUIDE services.

Priorities and Scope

- Focus on cognition
  - Other workup (e.g., functional or neuropsychiatric assessment, important but out of scope)
- Focus on detection of MCI, not just dementia, for DCA performance recommendations
- Focus on in-clinic, supervised DCAs first, excluding remote or unsupervised DCAs
- Focus on recommendations for use cases, test characteristics, and performance standards rather than implementation (separate)



CEOi workgroup for remote/at-home DCAs



CEOi workgroup for DCA implementation

Defining the Value of DCAs

Scalability and Accessibility

- Potential for integration with EMR systems to facilitate documentation and monitoring over time.
- Potential to increase cultural, linguistical and generational sensitivity with easier programing of alternate stimuli and languages.
- Can be administered by a wider range of HCPs with less training, fewer steps, no complex scoring, easy to interpret reports.
- Automated testing, scoring, and documentation could save HCPs time.

Improved Accuracy

- DCAs allow for immediate, automated scoring and normative comparisons
- Ability to capture more subtle or nuanced features of cognitive processes.
- Easier programing and administration for repeat testing to facilitate clinical monitoring over time.
- AI methods such as deep learning may enable faster and potentially more sensitive analysis of data and allow for the integration of cognitive data into risk prediction algorithms.

Where are the gaps?

- Careful, expert and stakeholder informed test development
- Independent and rigorous validation work in the population of intended use
- Transparent scoring processes and normative data
- Accounting for variations in digital literacy, sensory and motor function, demographic factors including race, ethnicity and education level
- Data on cost effectiveness

Clinical Contexts of Use

Clinical Contexts of Use
Cognitive Impairment Detection: HCP-initiated DCA* to detect any possible cognitive impairment as an initial first step to gauge whether further evaluation is needed. Typically used in the absence of a reported concern (e.g., routine, AWV assessment).
MCI/Dementia Diagnostic Aid: HCP-initiated DCA with sufficient sensitivity to aid in a diagnosis of a cognitive syndrome (i.e., MCI or dementia) by characterizing the degree of impairment. Typically used in the presence of a cognitive concern**, in conjunction with a comprehensive workup†
Profile Characterization Aid: HCP-initiated DCA to aid in the evaluation of etiology by providing information on the cognitive profile. Typically used after cognitive impairment has been confirmed, in conjunction with a comprehensive workup†

**All DCAs to be initiated based on shared decision making with patient.*
***Concerns reported from patient, caregiver, or provider*

TEST CHARACTERISTICS

	Cognitive Impairment Detection	MCI/Dementia Diagnostic Aid	Profile Characterization Aid
What is the test measuring? (what needs to be validated at a minimum)	Single or multidomain cognitive function - discriminates CI from CU	Multidomain cognitive function, including information on severity	Discrimination among cognitive domains (cognitive profile)
Target use settings	Primary care: Frequent; during an office visit by PCP or trained HCP (routine visits, Medicare AWV) Specialist: Infrequent	Primary care: Frequent; during an office visit by PCP Specialist: Frequent; during an office visit by dementia specialist	Primary care: Infrequent Specialist: Frequent; during an office visit by dementia specialist
Target population	Person *without* a recognized cognitive concern	Person *with* a recognized cognitive concern	Person with diagnosis of cognitive impairment Or uncertainty after prior testing
DCA test duration	~3-5 minutes	~10-20 minutes	~40 minutes or more
Intended use	**Positive**: indicates concern for cognitive impairment, evaluate further for confirmation. **Negative**: lower probability of cognitive impairment, continue to follow and focus on brain health interventions.	**Positive**: prompts a treatment plan including treatable causes and other interventions to promote brain health; primary care should consider referring to specialty care. **Negative**: Low likelihood for CI, continue to follow and focus on brain health interventions.	Test results will characterize the profile of affected domains to aid in determination of underlying etiology (e.g., MCI due to AD) and assist with selecting appropriate treatment and support plans.
Benchmark	Neuropsychological test battery	Neuropsychological test battery	Neuropsychological test battery
Comparative non-digital tool	Mini Cog or similar test	MoCA or similar test	Testing from specialist neuropsychological evaluation
Acceptable performance for accuracy	Sensitivity: 80% to detect cognitive impairment Specificity: 85%	Sensitivity: 85% to detect MCI/dementia Specificity: 90%	Sensitivity: 85% to detect MCI due to AD Specificity: 90%

Priorities for Design and Development

Validation	Recommendations
Normative data	• Normative data should come from large samples broadly representative of the general population. • Neuropsychological test batteries are recommended as the reference standard for DCAs and should be validated in demographically representative, longitudinal cohorts that reflect the DCA's intended use.
Diverse adaptation	• Validation should encompass diverse cultures, geographic regions, languages, socioeconomic backgrounds, education levels, risk factors, and varying degrees of technological familiarity, using culturally appropriate presentation and stimuli.
Reliability	• Test-retest reliability in the expected use settings should be established for all DCAs to ensure results are not confounded by environmental factors or random error.
Evaluation	• Implementation and dissemination studies represent best practices for assessing real-world performance.

Priorities for Design and Development

Results Reporting	Recommendations
Detection DCA	• Automated report for provider should clearly indicate whether cognitive impairment is a concern or unlikely, with recommendations for continued monitoring following a normal result. • EHR integration/templating of results is encouraged. • Sharing patient results through EHR integration is a desirable capability, to be implemented at the discretion of the healthcare system or provider.
Diagnostic Aid DCA & Profile Characterization Aid DCA	• Automated report for provider should include information on severity of impairment (Diagnostic Aid DCA) or the pattern and severity of impairment in different cognitive domains (Profile Characterization Aid DCA). • EHR integration/templating of results is encouraged. • Test results should be contextualized relative to normative benchmarks applied. • Providers should interpret and communicate results directly to patients. • Shared decision-making and discussions throughout the diagnostic process should be promoted, recognizing variations in clinical approaches.

Future Directions

For DCA developers and researchers:



- **Developing and validating DCAs for staging cognitive impairment severity (CoU2).**
- **Adoption of developing and validating DCAs in the population of intended use as a best practice.**
- **Longitudinal validation of DCAs in clinical settings.**

Additional Areas for Recommendations & Standardization:



- **DCA dissemination and implementation research and guidelines.**
- **Unsupervised and remote use DCA platforms and tools.**

Thank you!

DCA Workgroup Core Team

CEOi Support Team

Benjamin Tiede

Emily Scholler

Katherine Partrick

Citations:

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Additional references for today's talk can be found in the manuscript references