

American Geriatrics Society Feedback – Use of Cognitive Tests for the Early Detection of Cognitive Impairment in Older Adults in Primary Care Clinical Practice Guideline Submitted July 11, 2025

The American Geriatrics Society (AGS) appreciates the opportunity to submit our feedback to the Alzheimer's Association (AA) for the recommendations within its evidence-based clinical practice guideline (CPG) on the <u>Use of Cognitive Tests for the Early Detection of Cognitive Impairment in Older</u> <u>Adults in Primary Care</u> (see Appendix on page 11 for draft AA CPG).

Founded in 1942, AGS is a national, not-for-profit society of geriatrics healthcare professionals dedicated to improving the health, independence, and quality of life of older people. Our 6,000+ members include geriatricians, geriatrics nurse practitioners, social workers, family practitioners, physician associates, pharmacists, and internists who are pioneers in advanced-illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons. AGS is an anti-discriminatory organization. We believe in a society where we all are supported by and able to contribute to our communities, and bias and discrimination no longer impact healthcare access, quality, and outcomes for older adults and their care partners. AGS leads efforts to incorporate attention to older adults living with multiple chronic conditions into research^{1,2} and clinical care^{3,4} and is a champion for improving attention to the unique health care needs of older adults in workforce training.^{5,6} We believe that understanding disease across the lifespan⁷ is important to extending healthspan—the time someone lives in generally good health—for all of us as we age.

An important framework for how geriatrics health professionals care for older adults is the Geriatrics 5Ms.⁸ Our members are on the frontlines of caring for older Americans, many of whom are living with multimorbidity, advanced illness, and/or with complicated biopsychosocial issues. The Geriatrics 5Ms informed the development of the 4Ms of age-friendly care (What Matters, Medications, Mentation, and Mobility) of the Age-Friendly Health Systems movement which seeks to reimagine the 21st century health system so as to provide care that is age-friendly, respects the goals and preferences of the older adult, and meaningfully and substantially includes family caregivers in the plan of care.⁹

https://www.americangeriatrics.org/sites/default/files/Letters%20to%20House%20and%20Senate%20Appropriations%20Lead ership%20on%20FY%202025%20Funding%20for%20Geriatrics%20Workforce%20Training%20Programs.pdf

¹ Advancing Geriatrics Research: AGS/NIA Conference Series. American Geriatrics Society. Accessed July 9, 2025. <u>https://www.americangeriatrics.org/programs/advancing-geriatrics-research-agsnia-conference-series</u>

² The AGS/AGING Learning Collaborative. AGS CoCare. Accessed July 9, 2025.

https://mccresearch.agscocare.org/what_is_the_ags_aging_learning_collaborative

³ American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity. Guiding principles for the care of older adults with multimorbidity: an approach for clinicians. *J Am Geriatr Soc*. 2012;60(10):e1-e25. doi:<u>10.1111/j.1532-5415.2012.04188.x</u>

⁴ McNabney MK, Green AR, Burke M, et al. Complexities of care: common components of models of care in geriatrics. *J Am Geriatr Soc*. 2022;70(7):1960–72. doi:<u>10.1111/jgs.17811</u>

⁵ American Geriatrics Society. Written Testimony to Senate Labor-HHS-Education Appropriations Subcommittee on FY 2026 Funding for Geriatrics Workforce Training Programs. June 13, 2025. Accessed July 9, 2025.

⁶ AGS Advancing Health Care in Surgical and Related Medical Specialties. Special Collection. *J Am Geriatr Soc*. Accessed April 2, 2025. <u>https://agsjournals.onlinelibrary.wiley.com/hub/journal/15325415/agsadvancinggeriatrics</u>

⁷ Inclusion Across the Lifespan in Human Subjects Research. National Institutes of Health. Updated February 27, 2025. Accessed July 9, 2025. <u>https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/lifespan</u>

⁸ Tinetti M, Huang A, Molnar F. The Geriatrics 5M's: A new way of communicating what we do. *J Am Geriatr Soc*. 2017;65(9):2115. doi:<u>10.1111/jgs.14979</u>

⁹ Mate KS, Berman A, Laderman M, Kabcenell A, Fulmer T. Creating age-friendly health systems - a vision for better care of older adults. *Healthc*. 2018;6(1):4-6. doi:10.1016/j.hjdsi.2017.05.005

Below, we offer our observations and comments that reflect the most relevant and appropriate considerations for older adults, particularly those presenting to primary care settings.

GENERAL COMMENTS

Recommended Additional Comment Period

In general, providing the recommendations without the full text of the draft CPG made it challenging to review and provide meaningful comments on the proposed recommendations. The publicly available document for review excludes the explanation of the guideline panel's rationale for each recommendation as well as information on the evidence that was reviewed to arrive at the recommendations.

We recommend that AA provide a second, longer open comment period for the full text of the draft CPG. This would provide more transparency on the content and context of the guideline and allow reviewers a more meaningful opportunity to provide input into the updated recommendations for cognitive tests to utilize with older adults in primary care. Doing so would be in alignment with best practice recommendations from the Council of Medical Specialty Societies (CMSS), "<u>CMSS Principles for the Development of Specialty Society Clinical Practice Guidelines</u>" – a minimum 30 days for review and comment by external reviewers. Furthermore, recommendations for CPG development from both CMSS and the Institute of Medicine of the National Academies of Science, as outlined in "<u>Clinical Practice Guidelines</u>" with conflicts were resolved. Given that AA is a recipient of pharmaceutical industry funding, we encourage including a description of the policies and procedures in place that are focused on ensuring that the development of the CPG was independent of any influence from corporate and industry supporters or partners.

Person-Centered Care

AGS believes that decision-making needs to be individualized to the specific circumstances of an older adult that elicits and is guided by their values and preferences. This approach is in keeping with the principles of person-centered care which are to put patients at the center of decision-making about the tests and treatments that they will receive.¹⁰ In alignment with person-centered care and the Geriatrics 5Ms, this shared decision-making applies to determining if a cognitive screening test will be performed which should include a conversation about the purpose of testing, risks and benefits of such testing, need for a "timely" diagnosis versus early diagnosis, and impact of knowing about cognitive status on improving overall well-being and medical care. We have long championed that it is important for clinicians to address cognition during goals of care discussions and make decisions about whether a formal cognitive screening test is warranted, a matter of clinical judgment, in consultation with their patients. AGS recommends that the CPG lead with a statement that defines clinical care as whole-person evaluation and management that respects a person's goals and preferences.

Implementation Limitations

There are significant limitations to implementation of this guideline that AA should address in its introduction:

¹⁰ American Geriatrics Society Expert Panel on Person-Centered Care. Person-centered care: a definition and essential elements. *J Am Geriatr Soc.* 2016;64(1):15-18. doi:<u>10.1111/jgs.13866</u>

- The lack of accurate screening tools for people with limited educational attainment, whose primary language is not English, and/or who come from non-White racial groups.
- The limited Spanish-speaking workforce¹¹ to administer tests appropriately and limitations of Spanish version assessments due to the lack of robust data as well as the heterogeneity within the Spanish-speaking population resulting in national origin/culture-specific variations in sensitivity and specificity outcomes and cutoffs.^{12,13}
- The lack of training for the primary care workforce so that they have the skills and knowledge to administer and interpret the results of screening tests¹⁴ and are supported to add screening into workflow.

Age at Which Screening is to be Started

We are deeply concerned about the proposal that screening should start at age 55 and the lack of clarity around whether AA is suggesting that the entire population age 55+ (with some exceptions) should be screened for cognitive impairment in primary care regardless of whether a person presents with a cognitive concern. The document that AA shared for review did not provide any information on how the panel determined 55 would be the age at which screening would start nor a rationale for that age. However, the practice recommendations are worded in such a way as to suggest that the intent is that the entire population age 55+ should be screened, "In English- and Spanish-speaking adults aged 55 years and older presenting to primary and appropriate ambulatory care settings," with the exception of people that meet the definitions outlined in Remarks. Given the wording of Recommendations 1-3, AGS reviewers concluded that the overall intent of the CPG is that all English and Spanish- speaking adults over the age of 55 be assessed for cognitive impairment regardless of whether they are asymptomatic or have presented with a cognitive concern.

In light of that assessment, our top-level concerns are as follows:

- The title of the CPG states that the guideline is for clinicians caring for older adults. Practically speaking, the CPG then redefines the age at which one is considered to be an older adult to be 55.
- There is a lack of evidence for population-wide screening for cognitive impairment starting at age 55. Absent the text of the full guideline, it is unclear how age 55 was determined as the age at which primary care settings should begin population-wide screening for cognitive impairment and there is no evidence provided for this recommendation. In its 2020 recommendation statement on screening for cognitive impairment for older adults (defined as 65+), the United States Preventive Services Task Force (USPSTF) stated that there is insufficient evidence to recommend for or against cognitive screening¹⁵ and its latest Draft Research Plan released

¹¹ Velasco-Mondragon E, Jimenez A, Palladino-Davis AG, Davis D, Escamilla-Cejudo JA. Hispanic health in the USA: a scoping review of the literature. *Public Health Rev.* 2016;37(31):1-27. doi:<u>10.1186/s40985-016-0043-2</u>

¹² Burke SL, Grudzien A, Burgess A, Rodriguez MJ, Rivera Y, Loewenstein D. The utility of cognitive screeners in the detection of dementia spectrum disorders in Spanish-speaking populations. *J Geriatr Psychiatry Neurol.* 2020;34(2):102-118. doi:10.1177/0891988720915513

¹³ Paredes AM, Gooding A, Artiola i Fortuny L, et al. The state of neuropsychological test norms for Spanish-speaking adults in the United States. *Clin Neuropsychol.* 2021;35(2):236-252. doi:10.1080/13854046.2020.1729866

¹⁴ Alzheimer's Association. 2022 Alzheimer's disease facts and figures. *Alzheimers Dement*. 2022;18(4):700-789. doi:<u>10.1002/alz.12638</u>

¹⁵ US Preventive Services Task Force. Cognitive impairment in older adults: screening. February 25, 2020. Accessed July 11, 2025. <u>https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cognitive-impairment-in-older-adults-screening</u>

March 2025 for screening cognitive impairment in older adults applies to adults age 65 and older. $^{\rm 16}$

- The low prevalence of cognitive impairment at usual Medicare enrollment age¹⁷ and a lack of attention to a person's readiness to be screened.¹⁸
- The potential implications for younger people who are still working and receive a positive cognitive screen (e.g., stigma, job loss, inability to obtain insurance) and the potential of adding significant costs for patients and to the system for further testing.
- The fact that expanding screening to age 55 will place a burden on an already stressed workforce primary care. The reality is that the primary care workforce is not adequately supported to establish appropriate care pathways for positive test results on a cognitive screen because of time constraints,^{19,20} limited practice resources,^{21,22} and patients' lack of access to diagnostic services, clinicians with expertise in mild cognitive impairment (MCI) and dementia, and/or community-based services, ²³ particularly for historically underserved populations such as those in rural and urban areas with lower socioeconomic status.²⁴

AGS Recommendations:

- Change the title of the guideline so as to not introduce confusion about the age at which one is considered an older adult.²⁵
- Reconsider the scope and clinical question around the patient population that this guideline is intended to support and focus it on the segment of the population age 55 and older that is presenting to primary care with a cognitive concern.
- Provide the evidence that supports the recommendation to begin screening at age 55, regardless of whether AA decides to narrow that recommendation as suggested above.
- Include a clinical pathway that contextualizes cognitive screening tests within a clinical evaluation of a person that starts with shared decision-making around whether a screening test is needed. Cognitive screening tests should consistently be referred to as a tool that is available to clinicians who are clinically evaluating people who are presenting with cognitive complaints

https://cesr.usc.edu/sites/default/files/Implications%20of%20Alzheimer%27s%20Treatment%20for%20Organization%20and%2 0Payment%20of%20Medical%20Practices%20in%20the%20United%20States%20%282020%29.pdf

 ¹⁶ US Preventive Services Task Force. Cognitive impairment in older adults: screening. March 6, 2025. Accessed July 8, 2025.
 <u>https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-research-plan/cognitive-impairment-older-adults</u>
 ¹⁷ Hale JM, Schneider DC, Mehta NK, Myrskyla M. Cognitive impairment in the U.S.: lifetime risk, age at onset, and years impaired. *SSM Popul Health*. 2020;11:100577. doi:10.1016/j.ssmph.2020.100577

¹⁸ Fowler NR, Frame A, Perkins AJ, et al. Traits of patients who screen positive for dementia and refuse diagnostic assessment. *Alzheimers Dement (Amst).* 2015;1(2):236-241. doi:<u>10.1016/j.dadm.2015.01.002</u>

¹⁹ Mattke S, Wang M. Implications of Alzheimer's treatment for organization and payment of medical practices in the United States. USC Dornsife Center for Economic and Social Research; 2020.

 ²⁰ JaKa MM, Rossom RC, Borson S, et al. Confidence in diagnosing and managing care for cognitive impairment in primary care: a survey comparing barriers by primary care clinician type. *Fam Pract.* 2024;41(5):761-769. doi:<u>10.1093/fampra/cmae043</u>
 ²¹ Bernstein A, Rogers KM, Possin KL, et al. Primary care provider attitudes and practices evaluating and managing patients with

neurocognitive disorders. *J Gen Intern Med*. 2019;34(9):1691-1692. doi:10.1007/s11606-019-05013-7 ²² Sabbagh MN, Boada M, Borson S, et al. Early detection of mild cognitive impairment (MCI) in primary care. *J Prev Alz Dis*. 2020;7(3):165-170. doi:10.14283/jpad.2020.21

 ²³ Drabo EF, Barthold D, Joyce G, Ferido P, Chui HC, Zissimopoulos J. Longitudinal analysis of dementia diagnosis and specialty care among racially diverse Medicare beneficiaries. *Alzheimers Dement*. 2019;15(11):1402-1411. doi:10.1016/j.jalz.2019.07.005
 ²⁴ Sabbagh MN, Boada M, Borson S, et al. Early detection of mild cognitive impairment (MCI) in primary care. *J Prev Alz Dis*. 2020;7(3):165-170. doi:10.14283/jpad.2020.21

²⁵ Frey T, Young RK. Correct and preferred usage. In: Christiansen S, Iverson C, Flanagin A, et al. *AMA Manual of Style: A Guide for Authors and Editors.* 11th ed. Oxford University Press; 2020. Accessed July 11, 2025.

https://academic.oup.com/amamanualofstyle/book/27941/chapter/207567296?login=false#521739388

and that the results should always be interpreted within the clinical context as we outlined in our <u>AGS recommendations</u> for AA's draft CPG on the <u>Use of Blood-based Biomarkers for</u> <u>Alzheimer's Disease in Specialty Care Settings</u>.</u>

Address the impact on the primary care workforce of these recommendations inclusive of
potential solutions for increasing recruitment into primary care. Furthermore, while cognitive
screening may support increased identification of patients with cognitive concerns—via
subsequent cognitive tests or blood-based biomarkers—there are significant challenges to
screening in primary care, as mentioned in our top-level concerns, that need to be addressed
concurrently with recommendations that include placing additional screening requirements on
the primary care workforce.

<u>Equity</u>

The guideline methodology indicates that the panel discussed increased health equity as one of the "evidence-to-decision factors" in relation to cognitive testing generally. Concomitantly, the panel determined that one of the limitations of the evidence-to-decision process was generalizability of findings to more diverse populations. Considering the racial and ethnic disparities in the prevalence of Alzheimer's disease (AD) and AD related dementias (ADRD) among historically underserved populations, the increasing diversity among older people,²⁶ and the lack of reliability of cognitive screening instruments in diverse populations,²⁷ it is essential to explicitly call out whether age, gender, and racial and ethnic representation in the data is sufficient for applicability of the recommendations across populations. This is particularly important given the lack of accurate screening tools for people with limited educational attainment,^{28,29} whose primary language is not English, or who come from non-White racial groups is well-documented.^{30,31}

COMMENTS ON RECOMMENDATIONS 1-4

Role of Cognitive Tests

As noted above, we recommend that the CPG include a clinical pathway that contextualizes screening within the clinical workflow of assessing someone who is presenting with concerns about cognitive impairment. The CPG should consistently recognize and frame the role of cognitive screening tests as a second step in the clinical evaluation of patients for cognitive impairment (including MCI and dementia). Screening should always follow shared decision-making around whether a patient wishes to be screened, and results should always be interpreted through a whole person lens that is focused on what matters to the person.

We have recommended (in our General Comments) that AA limit this CPG to people who are presenting with cognitive impairment. Regardless of whether AA limits the population to be tested in this way, it is

 ²⁶ Matthews KA, Xu W, Gaglioti AH, et al. Racial and ethnic estimates of Alzheimer's disease and related dementias in the United States (2015–2060) in adults aged ≥65 years. *Alzheimers Dement*. 2019;15(1):17-24. doi:10.1016/j.jalz.2018.06.3063
 ²⁷ Sabbagh MN, Boada M, Borson S, et al. Early detection of mild cognitive impairment (MCI) in primary care. *J Prev Alz Dis*. 2020;7(3):165-170. doi:10.14283/jpad.2020.21

²⁸ Pellicer-Espinosa I, Díaz-Orueta U. Cognitive screening instruments for older adults with low educational and literacy levels: a systematic review. J Appl Gerontol. 2021;41(4):1222-1231. doi:<u>10.1177/07334648211056230</u>

²⁹ Tavares-Júnior JWL, de Souza ACC, Alves GS, Bonfdaini JDC, Siqueira-Neto JI, Braga-Neto P. Cognitive assessment tools for screening older adults with low levels of education: a critical review. *Front Psychiatry*. 2019;10(878):1-12. doi:10.3389/fpsyt.2019.00878

³⁰ Arévalo SP, Kress J, Rodriguez FS. Validity of cognitive assessment tools for older adult Hispanics: a systematic review. *J Am Geriatr Soc.* 2020;68(4):882-888. doi:10.1111/jgs.16300

³¹ Lim S, Chong S, Min D, et al. Alzheimer's disease screening tools for Asian Americans: a scoping review. *J Appl Gerontol.* 2020;40(10):1389-1398. doi:10.1177/0733464820967594

important that the CPG define the appropriate patient population for a cognitive screening test and consistently convey that in clinical care a cognitive screening test:

- 1. Is a tool that is available to health professionals who are clinically evaluating someone presenting with a cognitive complaint **and** who has agreed to be tested.
- 2. The results of cognitive screening should always be interpreted within the clinical context of that person, taking into account other health conditions and what matters most to that person.

Evidence Certainty

AGS is concerned that the summary of findings and accuracy judgments for the cognitive assessments as well as the balance of effects with available data that the panel evaluated indicates that all tests evaluated have significant limitations or have not been sufficiently evaluated. Nearly all tests failed applicability in real-world settings which is a limitation for implementation in primary care. In addition, the preference for "true positive" tests over "true negative" tests seemed to favor the maximum detection of MCI due to AD. Given AA states that a part of the rationale for this update is that there are disease altering therapies available for AD, this preference for "true positives" and the focus on population-wide screening of adults 55+ could be interpreted as reflecting an implicit bias towards detection of AD. If there is an explicit goal to identify and track individuals with MCI due to AD for biomarker testing and subsequent anti-amyloid therapy, that should be made apparent; apart from that, the panel's justification for their evaluation of the tests is necessary to understand the level of bias, if any.

We recommend a screening approach that allows clinicians to select the best test for the intended application of testing (e.g., identifying individuals who need a care partner to manage their own healthcare) for a specific population with consideration of alternatives and supplemented by other measures for evaluation. The intended application is important to understand given cognitive screening tests are not required to facilitate healthy brain behaviors as part of the overall foundation of clinical care.

SPECIFIC COMMENTS

Recommendations 1 and 2:

Prior to reviewing these recommendations, it would have been informative to see how the panel defined "accuracy" and "test effects" as well as understanding the populations that were evaluated and the evidence base that is supporting Recommendations 1 and 2. As noted in our General Comments, providing the full text of a draft CPG to reviewers is an important and recommended step when seeking external, public review, as is providing a 30-day comment period so that reviewers have adequate time to develop their comments.

For both recommendations, we recommend that AA modify the presentation of the statement about overall test effects since it is unclear if that statement applies to all tests in the recommendation or the last test listed in the recommendation.

Recommendation 1: In English- and Spanish-speaking adults aged 55 years and older presenting to primary and appropriate ambulatory care settings, the panel suggests <u>using either AD8 or SLUMS</u> over no screening for the early detection of cognitive impairment (including mild cognitive impairment and dementia) (conditional recommendation*, low certainty evidence for AD8 test accuracy, moderate certainty evidence for SLUMS test accuracy; very low certainty evidence for overall test effects).

As currently structured, there appears to be two recommendations made in Recommendation 1:

- a) All patients presenting to primary care and appropriate ambulatory settings should be screened; and
- b) The specific screening tests to use.

<u>Population to be Screened</u>: As discussed in our General Comments above, we reviewed Recommendation 1 through the lens suggested by the language of the recommendation which is that all English- and Spanish-speaking people aged 55 and older should undergo a cognitive screening test. As above, we recommend that AA narrow the recommendation on the population to be considered for a cognitive screening to those individuals who have presented with a cognitive concern and contextualize this recommendation as being one component of clinical evaluation of such individuals. AA should provide evidence of sufficient strength to justify a recommendation that the age at which screening for cognitive impairment begins should be 55 which is a significant extension of the time period for preventive screening.

<u>Recommended Tests</u>: The lack of a justification and evidence for Recommendation 1 made it difficult for AGS reviewers to understand how the panel chose the Eight-item Informant Interview to Differentiate Aging and Dementia (AD8) and the Saint Louis University Mental Status (SLUMS). This recommendation is identified as a conditional recommendation and notes the low certainty of the evidence and inaccuracy for AD8 and moderate certainty of evidence for SLUMS. Further, SLUMS is the least studied of all the screening tests included in the panel's analysis and there are extensive gaps in the evidence for SLUMS, yet the panel evaluated SLUMS favorably and suggested its use in Recommendation 1.

To ensure clarity about the purpose of using screening tests in the clinical evaluation of someone presenting with a cognitive concern, we recommend reiterating that screening tests are one component of clinical evaluation in the discussion and that tests alone do not substitute for an appropriate clinical evaluation by the clinician that is inclusive of shared decision-making as to whether a person needs to be screened.

Recommendation 2: In English- and Spanish-speaking adults aged 55 years and older presenting to primary and appropriate ambulatory care settings, the panel suggests <u>against</u> <u>using MIS, Mini-Cog,</u> <u>and MoCA</u> for the early detection of cognitive impairment (including mild cognitive impairment and dementia) (conditional recommendation, low certainty evidence for MIS test accuracy, low certainty evidence for MoCA test accuracy; very low certainty evidence for MoCA test accuracy; very low certainty evidence for overall test effects).

Population to be Screened: See General Comments and comments on Recommendation 1.

<u>Suggestions as to Tests Not to Use</u>: Cognitive screening, unlike blood glucose screening for diabetes (as an example), is not precise. There is a great deal of heterogeneity across the population being screened and more complexity than is typically encountered with biomedical diagnostic tests. Given that Recommendation 1 and Recommendation 2 are both conditional recommendations and the panel did not consider all available cognitive screening tests, we recommend that AA delete Recommendation 2 from the CPG.

Recommendation 3: In English- and Spanish-speaking adults aged 55 years and older presenting to primary and appropriate ambulatory care settings, the panel suggests <u>neither for or against using</u>

IQCODE and s-IQCODE for the early detection of cognitive impairment (including mild cognitive impairment and dementia) (conditional recommendation, low certainty evidence for IQCODE test accuracy, low certainty evidence for s-IQCODE test accuracy; very low certainty evidence for overall test effects).

Population to be Screened: See General Comments and comments on Recommendation 1.

<u>Recommended Tests</u>: The Questionnaire on Cognitive Decline in the Elderly (IQCODE) and the short version of IQCODE (s-IQCODE) are questionnaires for informants, which can be subject to unmeasured biases and confounding factors. We recommend that AA modify the language of this recommendation to reflect that these are tools that are administered to informants and not to the patient. In the discussion of the recommendation, AA should be explicit that there is a possibility of bias and confounders.

Remarks

Remark 1: Cognitive testing is not recommended in primary care or ambulatory settings for the following patients, including but not limited to: patients with delirium, agitation, acute or sleep deprivation, or those with unstable medical issues; patients receiving new or recently increased sedative medications or those actively using or withdrawing from drugs of abuse, in the middle of a major depressive episode; patients with an established diagnosis of cognitive impairment or already receiving treatments for cognitive decline; patients with any condition that interferes with having a clear sensorium would contraindicate a screening test.

The AGS recommendations are as follows:

- As stated in our General Comments, the focus of this CPG should be on screening in primary care of people presenting with cognitive concerns including an acknowledgment that all the tests evaluated were screening tools. For clarity, given that this CPG is focused on screening tools, we recommend that Remark 1 be revised to replace "testing" with "screening."
- <u>Delirium</u>: We recommend replacing "patients with delirium" with "patients in the presence of delirium" and noting that a screening for delirium should occur to confirm presence of delirium and avoid mislabeling. We believe that intent of the panel in including this patient population here was to ensure that the results are not confounded by acute effects not characteristic of the patient's baseline functioning.
- Routine cognitive screening is not recommended for asymptomatic individuals, and the
 available evidence is insufficient on how to move forward with care for those who are
 asymptomatic except for screening treatable causes, recommending a healthy lifestyle (e.g.,
 regular exercise), and managing vascular risk factors. Until there is evidence to support
 beneficial effects of population-wide cognitive screening (specifically administering cognitive
 screening tests to asymptomatic people), AGS recommends limiting the CPG
 recommendations to people presenting with a cognitive concern. In light of that, AGS further
 recommends that "patients who are asymptomatic" be added to the list of individuals not
 recommended for cognitive screening tests in the Remarks.

Table 2. Definitions for interpreting the certainty of the evidence and implementing strong vs.conditional recommendations

While there was no request for comments on Table 2, AGS believes that the table should reflect that it was adapted from the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Handbook. The CPG should also include a rationale for use of an adapted version of GRADE and how the panel utilized the table to determine certainty of the evidence and selecting strong or conditional for the recommendations.

AGS' feedback for specific definitions of strong vs. conditional recommendations are:

For Patients	Strong Recommendation Most patients in this situation would want the recommended course of action, and only a small proportion would not. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Conditional Recommendation Most patients in this situation would want the suggested course of action, but many would not.
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• The definitions for these recommendations would be more informative with additional details about how patients are affected by a strong recommendation versus a conditional recommendation beyond their desire for the "course of action" that is recommended.

For Clinicians	Strong Recommendation	Conditional Recommendation
	Most patients should receive this	Recognize that different choices will
	course of action. Adherence to this	be appropriate for individual
	recommendation, according to the	patients and that you must help
	guideline, could be used as a	each patient arrive at a
	quality criterion or performance	management decision consistent
	indicator.	with his or her values and
		preferences. Decision aids may be
		useful in helping patients make
		decisions consistent with their
		values and preferences.

• As emphasized above, AGS strongly supports shared decision-making that is guided by the patient's values and preferences in clinical care generally. However, it is unclear the distinct role of the patient's "value and preferences" as well as "management decision" in the panel's evaluation of the implications for clinicians for recommendations labeled as conditional.

For Policy	Strong Recommendation	Conditional Recommendation
Makers	The recommendation can be adapted	Policy making will require
	as policy in most situations.	substantial debate and the
		involvement of various
		collaborative parties.

• The definitions for policy makers are vague as to who is considered a policy maker, and it is not clear what the specific implications are under each type of recommendation. For example, if a strong recommendation can be adapted as policy in **most** situations, what should be done in circumstances that the recommendation cannot be adapted? And what would be the impacts on systems of care if these recommendations are adopted? For example, what if this CPG was used to inform the design of Medicare Wellness Visits without consideration of other preventive needs that may matter more to the person? As we commented above, there would need to be a parallel effort to ensure that primary care is supported to implement this CPG including attention to payment, modifications to clinical workflow, and the lack of a workforce with the requisite skills should someone need additional testing and evaluation due to a positive screen.

In making these comments, AGS understands the heavy toll of AD/ADRD on patients, care partners, and their families. While we agree with the importance of early detection of cognitive impairment, now is the time to implement public and professional education efforts that prepare society for the fact that some people may be diagnosed with AD yet never live to develop objective evidence of cognitive impairment or progress to meet clinical criteria for dementia.

Thank you for taking the time to review our feedback and recommendations. For additional information or if you have any questions, please do not hesitate to reach out.

APPENDIX

Alzheimer's Association's Evidence-based Clinical Practice Guideline on the Use of Cognitive Tests for the Early Detection of Cognitive Impairment in Older Adults in Primary Care

What is the ask:

- Panel recommendations and remarks (Table 1): Please review the information starting on Page 2. Use the online form to provide feedback on the content or presentation of what are to be the recommendations and associated remarks contained in the green sections in Table 1. Overall, we wish to understand if you believe the recommendations are 1) Clear and 2) Actionable and 3) If not, please provide suggestions for how to improve their usefulness for clinical decision-making. Your diverse perspectives are essential to ensuring the recommendations are practical, patient-centered, and reflective of real-world experiences. We have also provide a legend (Table 2) informing the interpretation and implementation of these draft recommendations by various users.
- Additional contextual information (Pages 6-10): We briefly describe the overview of the guideline development process, including systematic review methodology. In addition to finalized recommendations and remarks, a full reporting of panel disclosures, summary of findings tables, and methods will be submitted to a scientific journal and peer-reviewed by external reviewers before approval for publication.

Who should comment:

- Clinicians across all disciplines and specialities, researchers, patients, caregivers, and family members, patient advocates, health system representatives, healthcare administrators, policy-makers, and any individual or organization with an interest or expertise in this topic can comment.
- If multiple individuals within the same organization/agency wish to provide feedback, we strongly encourage submitting a *single, comprehensive, coordinated response* that integrates all perspectives. This helps ensure clarity and coherence for panel review.

How your comments will be used:

- The methods team and guideline panel will review all feedback received during the public comment period (June 30 July 11, 5 p.m. CDT). Comments that are within the scope of the guideline question and supported by the available evidence will be considered for incorporation into the final guidance. Revisions may be made to improve accuracy, clarity, or applicability.
- Following the publication of the final manuscript, all comments—de-identified where possible—will be made publicly available to promote transparency and acknowledge the contributions of collaborative parties.

Please scroll down to review an overview of the project and recommendations and remarks.

Overview of project:

Background: In 2013, the Alzheimer's Association published <u>recommendations</u> to support cognitive assessment during the Medicare Annual Wellness Visit, offering guidance on workflow, tool selection, and follow-up. Since then, advances in cognitive science, new disease-modifying therapies for AD, and increased emphasis on early detection prompted the Association to update these recommendations using the GRADE methodology. In Spring 2024, the Alzheimer's Association convened a guideline panel of clinical and subject-matter experts to develop an evidence-based clinical practice guideline on the use of cognitive tests in older adults in primary care. In collaboration with systematic review and guideline methodologists, the guideline panel developed the scope, purpose, target audience, and clinical questions for the guideline. In Summer 2025, the panel formulated draft evidence-based recommendations, now available for public comment, and are preparing manuscripts for submission to peer-reviewed journals.

Scope: The scope of this guideline focuses on patients 55 years and older presenting to primary care and appropriate ambulatory settings (i.e. geriatric medicine, psychiatry) in the United States. The recommendations do not apply to specialty care settings such as memory clinics or to patients who already have an established diagnosis of cognitive impairment.

Only index tests that are freely available and take 15 minutes or less to administer were included, and only English and Spanish versions were evaluated. Digital tests were excluded. Importantly, the target condition was defined as any cognitive impairment (vs. no cognitive impairment), including mild cognitive impairment and dementia.

Included tests:

- 5-Cog
- Eight-item Informant Interview to Differentiate Aging and Dementia (AD8)
- General Practitioner assessment of Cognition (GPCOG)
- Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) (including short version)
- Mini-Cog
- Memory Impairment Screen (MIS)
- Montreal Cognitive Assessment (MoCA) (including short version)
- Quick Dementia Rating System (QDRS)
- Rowland Universal Dementia Assessment Scale (RUDAS)
- Saint Louis University Mental Status (SLUMS)

Methodology: The Alzheimer's Association's methodological team followed the <u>GRADE approach</u> and the <u>Cochrane Handbook for Diagnostic Test Accuracy</u> to synthesize evidence (search conducted between January 1, 1999, to August 13, 2024), assess the certainty of the evidence, move from evidence to decisions, draft recommendations, and assign the strength of recommendations. A priori panel decisions included: development of clinical questions in PICO format, included index tests and reference standards, statistical plan for meta-analysis, and clinical thresholds for decision-making.

When discussing the body of evidence and drafting recommendations, the panel was blinded to all cognitive assessment names by using placeholders (e.g., Test 1, Test 2, etc.). The panel considered the benefits of true positive and true negative and the harms of false positive and false negative test results. A greater emphasis was placed on maximizing true positives (as opposed to true negatives) and minimizing false negatives (as opposed to false positives), as the intent is early identification and

differentiation of any cognitive impairment or related conditions. Methodologists <u>managed conflicts of</u> <u>interest</u> using predetermined rules set by the Alzheimer's Association to minimize bias.

Recommendations: The panel drafted recommendations that address which cognitive test(s) to use in English and Spanish-speaking adults aged 55-years and older presenting to primary and appropriate ambulatory care settings (i.e. geriatric medicine, psychiatry), in the United States including those aged 65+ as part of an Medicare Annual Wellness Visit (Table 1). A guide for interpreting the certainty of the evidence and strength of recommendations can be found in Table 2.

 Table 1. Clinical question and recommendations and remarks for decision-making.

Clinical question (closed for comment)

In English- and Spanish-speaking adults aged 55 years and older presenting to primary and appropriate ambulatory care settings, which test (i.e., 5-Cog, AD8, GPCOG, IQCODE, s-IQCODE Mini-Cog, MIS, MoCA, s-MoCA, QDRS, RUDAS, and SLUMS)¹ should be used for the early detection of cognitive impairment (including MCI and dementia)?

Recommendations (open for public comment)

Recommendation 1: In English- and Spanish-speaking adults aged 55 years and older presenting to primary and appropriate ambulatory care settings, the panel suggests **using either AD8 or SLUMS** over no screening for the early detection of cognitive impairment (including mild cognitive impairment and dementia) (conditional recommendation*, low certainty evidence for AD8 test accuracy, moderate certainty evidence for SLUMS test accuracy; very low certainty evidence for overall test effects).

Recommendation 2: In English- and Spanish-speaking adults aged 55 years and older presenting to primary and appropriate ambulatory care settings, the panel suggests **against using MIS, Mini-Cog, and MoCA** for the early detection of cognitive impairment (including mild cognitive impairment and dementia) (conditional recommendation, low certainty evidence for MIS test accuracy, low certainty evidence for Mini-Cog test accuracy, very low certainty evidence for MoCA test accuracy; very low certainty evidence for overall test effects).

Recommendation 3: In English- and Spanish-speaking adults aged 55 years and older presenting to primary and appropriate ambulatory care settings, the panel suggests <u>neither</u> for or against using IQCODE and s-IQCODE for the early detection of cognitive impairment (including mild cognitive impairment and dementia) (conditional recommendation, low certainty evidence for IQCODE test accuracy, low certainty evidence for s-IQCODE test accuracy; very low certainty evidence for overall test effects).

Recommendation 4: The panel makes <u>no recommendation regarding the use of 5-Cog</u>, <u>GPCOG, QDRS, RUDAS, and short MoCA</u> for English- and Spanish-speaking adults aged 55 years and older presenting to primary and appropriate ambulatory care settings (knowledge gap).

Remarks

- Cognitive testing is not recommended in primary care or ambulatory settings for the following patients, including but not limited to: patients with delirium, agitation, acute or sleep deprivation, or those with unstable medical issues; patients receiving new or recently increased sedative medications or those actively using or withdrawing from drugs of abuse, in the middle of a major depressive episode; patients with an established diagnosis of cognitive impairment or already receiving treatments for cognitive decline; patients with any condition that interferes with having a clear sensorium would contraindicate a screening test.
- These recommendations are not intended to cover acutely ill populations (e.g., urgent care, emergency department) or referred populations seen in specialty clinics (e.g., memory disorder clinics, neurology clinics). The index tests may perform differently in referred populations.

Footnotes:

1. Comparison used for evidence synthesis: Any included cognitive assessment (index tests) vs clinical diagnosis of MCI or dementia using any recognized classification system or consensus diagnosis (reference standards).

Table 2. Definitions for interpreting the certainty of the evidence and implementing strong	j vs.
conditional recommendations.	

DEFINITION OF CERTAINTY OF THE EVIDENCE				
Category	Definition			
High	Very confident that the true effect lies close to that of the estimate of the effect.			
Moderate	Moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.			
Low	Confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.			
Very Low	Very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of the effect.			
DEFINITION OF STRONG VS. CONDITIONAL RECOMMENDATIONS AND IMPLICATIONS FOR COLLABORATIVE PARTIES				
Implications	Strong Recommendations Conditional Recommendations			

For Patients	Most patients in this situation would want the recommended course of action, and only a small proportion would not. Formal decision aids are not likely to be needed to help individuals make decisions consistent with their values and preferences.	Most patients in this situation would want the suggested course of action, but many would not.	
For Clinicians	Most patients should receive this course of action. Adherence to this recommendation, according to the guideline, could be used as a quality criterion or performance indicator.	Recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping patients make decisions consistent with their values and preferences.	
For Policy Makers	The recommendation can be adapted as policy in most situations.	Policy making will require substantial debate and the involvement of various collaborative parties.	
Researchers	The recommendation is supported by credible research or other convincing judgments that make additional research unlikely to alter the recommendation. On occasion, a strong recommendation is based on low or very low certainty in the evidence. In such instances, further research may provide important information that alters the recommendations.	The recommendation is likely to be strengthened (for future updates or adaptation) by additional research. An evaluation of the conditions and criteria (and the related judgments, research evidence, and additional considerations) that determined the conditional (rather than strong) recommendation will help to identify possible research gaps.	

Conclusions: The panel judged the benefits of using AD8 or SLUMS in patients aged 55 and older presenting to primary care to outweigh the harms, and therefore made conditional recommendations for the use of either test. The panel judged the harms of using MIS, Mini-Cog, and MoCA to outweigh the benefits and made conditional recommendations against their use. The panel judged the benefits and harms of using IQCODE and s-IQCODE to be balanced and therefore does not recommend for or against either test. Lastly, the panel identified no studies meeting eligibility criteria in primary care or community-based settings on the use of 5-Cog, GPCOG, QDRS, RUDAS, and short MoCA and chose not to formulate recommendations for those tests.

Next Steps: This clinical practice guideline (and associated systematic review) will be published later this year and will provide finalized recommendations based on the best available evidence.

-----BELOW IS CONTEXTUAL INFORMATION FOR REFERENCE ONLY------

Additional information on systematic review and guideline methodology:

Index tests of interest for which evidence was sought (including short forms):

- 5-Cog
- AD8
- GPCOG
- IQCODE
- Mini-Cog
- MIS
- MoCA
- QDRS
- RUDAS
- SLUMS

Excluded index tests:

- Tests that only assess function and behavior
- Tests that rely solely on subjective assessments
- Tests only available in digital format
- Tests requiring a license for use
- Combinations, composites, or components of index tests
- Specific excluded tools include:
 - Mini-Mental State Examination (MMSE)
 - Clock Drawing Test
 - Cognitive Function Index

Excluded settings:

• Specialty care settings/referred populations

Reference Standards:

- Clinical diagnosis using recognized classification systems or consensus diagnosis. For example:
 - Petersen criteria (MCI)
 - DSM criteria (dementia)
 - NINCDS-ADRDA criteria (Alzheimer's)
 - Clinical Dementia Rating (CDR)

Outcomes:

- Sensitivity and specificity
- Positive/negative predictive value
- Area under the curve (AUC)
- Likelihood ratios
- Frequencies of TP, FP, TN, FN

A priori decisions made by the panel for decision making:

The panel set thresholds for test accuracy based on the number of false negative and false positive results they would be willing to accept:

- False negative threshold: 5 per 100
- False positive threshold: 10 per 100

The panel agreed on a prevalence of <u>34.2%</u> for cognitive impairment, which was used to estimate the number of true positives, true negatives, false positives, and false negatives each test would result in based on data analyzed in the systematic review.

For decision-making, the panel placed a greater emphasis on maximizing true positives (as opposed to true negatives) and minimizing false negatives (as opposed to false positives), as the intent is early identification and differentiation of any cognitive impairment or related conditions.

The panel decided to only use community and primary care data to inform decision-making for which tests to recommend for primary care. Although the systematic review identified studies evaluating the cognitive assessments in specialty care or referred populations, the panel agreed that these settings are too indirect for the clinical question, and the pre-test probability will differ from that of primary care.

Results of main analysis:

15 observational studies were identified that assessed the accuracy of the cognitive tests in the population and setting of interest (i.e., patients 55 years and older in primary care or community-based settings). Where possible, data were pooled across studies to estimate a single sensitivity and specificity. When pooling was not possible, ranges were reported **(Table 3)**.

Test	N studies (n participants) Pooled or range	Sensitivity	Specificity	TP/TN/FP/FN frequencies ¹ (95% CI)	Accuracy judgement	Certainty of the evidence
AD8	3 ^{2,3,4} (881) Pooled	0.77 (95% CI: 0.67-0.85)	0.87 (95% CI: 0.82-0.91)	TP: 26 (23 to 29) TN: 57 (54 to 60) FN: 8 (5 to 11) FP: 9 (6 to 12)	Inaccurate	Low
IQCODE	1⁵ (160)	0.71 (95% CI: 0.61-0.80)	0.74 (95%CI: 0.62-0.84)	TP: 24 (21 to 27) TN: 49 (41 to 55) FN : 10 (7 to 13) FP: 17 (11 to 25)	Very inaccurate	Low
Mini-Cog	2 ^{6,7} (721) Range	0.39 to 0.50	0.73 to 0.78	TP: 13 to 17 TN: 48 to 51 FN: 17 to 21 FP: 15 to 18	Very inaccurate	Low
MIS	2 ^{6,8} (747) Range	0.17 to 0.73	0.87 to 0.98	TP: 6 to 25 TN: 57 to 64 FN): 9 to 28 FP: 2 to 9	Very inaccurate	Low
MoCA	5 ^{9,10,11,12,13} (1,040) Range	0.57 to 0.98	0.10 to 0.72	TP: 19 to 34 TN: 7 to 47 FN: 0 to 15 FP: 19 to 59	Very inaccurate	Very low
s-IQCODE	2 ^{14,15} (1,004)	0.55 to 0.80	0.82 to 0.93	TP: 19 to 27 TN: 54 to 61 FN: 7 to 15	Inaccurate	Low

Table 3. Summary of findings and accuracy judgments for the cognitive assessments.

	Range			FP: 5 to 12		
SLUMS	1 ¹⁷ (433)	0.98 (95% CI: 0.93-1.00)	0.61 (95% CI: 0.55-0.67)	TP:34 (32 to 34) TN: 40 (36 to 44) FN:0 (0 to 2) FP: 26 (22 to 30)	Accurate	Moderate
5-Cog	No included studies	-	-	-	-	-
GPCOG	No included studies	-	-	-	-	-
QDRS	No included studies	-	-	-	-	-
RUDAS	No included studies	-	-	-	-	-
s-MoCA	No included studies	-	-	-	-	-

1. True positive, true negative, false negative, false positive; based on a prevalence of 34.2%

- 2. <u>Galvin 2005</u>
- 3. Malmstrom 2009
- 4. <u>Tainta 2022</u>
 5. <u>Cruz-Orduna</u> Cruz-Orduna 2012
- 6. Holsinger 2012
- 7. Kaufer 2008
- 8. <u>Carnero-Pardo 2011</u>
- 9. <u>Alfano 2022</u> 10. <u>Katz 2021</u>
- 11. McLennan 2011
- 12. <u>Rossetti 2019</u> 13. Stimmel 2024
- 14. Avalon 2011
- 15. Grober 2017
- 16. <u>Tariq 2006</u>

Additional contextual factors considered as part of GRADE evidence-to-decision framework:

Additional contextual factors, using the GRADE approach, regarding the use of each cognitive assessment (vs. no testing) were considered. We acknowledge this section is methodologically jargon-heavy, and will fully explain our methodology, the evidence, and our judgments on the evidence in our final manuscripts.

Desirable and undesirable effects (i.e., benefits and harms) of each test with available data were judged by the panel based on downstream consequences of true positives, true negatives, false negatives, and false positives. Desirable effects, undesirable effects, and accuracy were all considered when judging the balance of effects (Table 4).

Test	Desirable Effects	Undesirable Effects	Accuracy*	Balance of effects
AD8	Moderate	Small	Inaccurate	Probably favors using AD8
IQCODE	Moderate	Small	Very inaccurate	Does not favor either/balanced effects
Mini-Cog	Trivial	Large	Very inaccurate	Probably favors not using Mini-Cog
MIS	Trivial	Moderate	Very inaccurate	Probably favors not using MIS
MoCA	Small	Moderate	Very inaccurate	Probably favors not using MoCA
s-IQCODE	Small	Small	Inaccurate	Does not favor either/balanced effects
SLUMS	Large	Small	Accurate	Probably favors using SLUMS

Table 4. Balance of effects for cognitive assessments with available data.

*Based on true positives, true negatives, false positives, false negatives, sensitivity, and specificity

Other evidence-to-decision factors were discussed as they relate to cognitive testing more generally (i.e., unlikely to differ depending on which assessment is given). This information will be provided in the manuscript, and final judgments for those factors are reported below:

- Certainty of the evidence of management's effects: How certain is the panel that treatment and management for MCI and dementia is effective? *Low to very low certainty.*
- Certainty of the evidence of the link between test result and management: How certain is the panel that patients who are positive based on a cognitive assessment will proceed to further testing/diagnosis and management? *Low to very low certainty.*
- Overall certainty of test effects: Based on the certainty of the evidence of management's effects and the link between test result and management: *Low to very low certainty.*
- Patients' values and preferences: Is there important uncertainty about or variability in how much people value the main outcomes? *Possibly important uncertainty or variability.*
- Resources required: How large are the resource requirements/costs? Negligible costs.
- Cost-effectiveness: Does the cost effectiveness of using cognitive assessments favor their use or non-use? *No included studies.*
- Equity: What would be the impact on health equity? Increased
- Acceptability: Is the use of cognitive assessments acceptable to collaborative parties? Yes.
- Feasibility: Are cognitive assessments feasible to implement? Varies.

Limitations of the evidence synthesis and evidence-to-decision process:

The evidence base was restricted to studies published in English, which may have excluded relevant data published in other languages, such as Spanish. Additionally, only index tests administered in English and Spanish were considered, potentially limiting the generalizability of findings to more diverse populations. The inclusion criteria also restricted the population to individuals aged 55 years and older, which may not capture data relevant to younger individuals. However, dementia occurring before age 55 is typically attributed to early-onset forms, which often have different etiologies, including those not related to AD.

The Mini-Mental State Examination (MMSE) was not included in this review, which limits its completeness. The MMSE was excluded due to licensing requirements that restrict its accessibility in many primary care and community-based settings. Furthermore, this review and guideline did not consider or evaluate the performance of repeat administrations of the index tests over time, did not consider adjustments for potential confounding factors such as age or education, and did not evaluate different cutoffs for index tests as this is outside the scope of the clinical question. Finally, because of significant heterogeneity among the included studies, it was not possible to pool data across studies for all cognitive tests, underscoring the need for further research in these areas.

Contact information and authors list:

Contact: Please use the online form to provide feedback on this guideline. For any general questions about the Alzheimer's Association's Guideline Development Program, please contact Malavika Tampi, Director, Clinical Practice Guidelines Program and Methodology Lead (<u>mptampi@alz.org</u>).

This particular document was prepared by the following guideline panel and methodology team members. Additional authors contributed to the systematic review and guideline manuscripts and will be appropriately included in publications along with conflict of interest disclosure forms for all.

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