THE GERONTOLOGICAL SOCIETY OF AMERICA WORKGROUP ON COGNITIVE IMPAIRMENT DETECTION AND EARLIER DIAGNOSIS

REPORT AND RECOMMENDATIONS

THE GERONTOLOGICAL SOCIETY OF AMERICA®

The Gerontological Society of America Workgroup on Cognitive Impairment Detection and Earlier Diagnosis

Report and Recommendations

The findings and conclusions in this report are those of the workgroup and do not necessarily represent the views of the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Health Resources and Services Administration, the National Institutes of Health, the National Institute on Aging, or the National Institute of Neurological Disorders and Stroke.

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1. INTRODUCTION: "WHY THIS REPORT?"

a. Purpose of This Report

This report addresses a serious but frequently overlooked gap in health care for the rapidly aging population of the United States: how older adults at risk for, or with signs and symptoms of, Alzheimer's disease and related dementias are inadequately assessed for cognitive impairment during routine visits with their primary care providers (PCPs).[1] Increased detection of cognitive impairment is an essential first step toward earlier diagnosis of Alzheimer's and related dementias. Yet available evidence indicates that cognitive impairment is severely underdetected by PCPs. Unless cognitive impairment is detected, people who have the condition are unlikely to receive a diagnostic evaluation to determine the cause of their cognitive impairment, and those who have Alzheimer's or another dementia are unlikely to receive a diagnosis. Without a diagnosis, older people with Alzheimer's and related dementias and their family caregivers[2] are unlikely to benefit from post-diagnostic medical care that takes into account the person's cognitive impairment and other dementia-related symptoms, or from community-based educational, support, and skill-building resources that often lead to improved health-related outcomes and well-being. The recommendations and related action steps discussed in this report are intended to lay out a practical and successful way forward in greatly increasing the number of PCPs across the country who routinely use evidence-based assessment tools to detect cognitive impairment during office visits with their older patients.

This report was written by members of a workgroup assembled by The Gerontological Society of America (GSA) to tackle this problem principally, but not exclusively, by recommending ways that brief, evidence-based assessment tools to detect cognitive impairment could be routinely incorporated into the Medicare Annual Wellness Visit (AWV). The rationale for focusing on the AWV is that it is now a health care benefit available to all Americans insured by the Medicare Part B program, and the Medicare population is most likely to benefit from increased detection of cognitive impairment and earlier diagnosis of dementia due to the age-associated nature of dementia-related disorders. Recommended action steps discussed in this report also respond directly to objectives and action steps specified in the National Plan to Address Alzheimer's Disease (U.S. Department of Health and Human Services [HHS], 2012), which was mandated by the National Alzheimer's Project Act, and annual updates to that plan (HHS, 2013, 2014).

b. Epidemiology and Consequences of Alzheimer's Disease and Related Dementias

Estimates vary considerably for the total number of older Americans living with dementia caused by Alzheimer's disease, vascular conditions, Lewy body disease, frontotemporal degeneration, and combinations of these and other diseases and conditions. The Alzheimer's Association reports that in 2014, 5.2 million Americans of all ages had Alzheimer's disease, and Alzheimer's disease accounts for an estimated 60% to 80% of all cases of dementia (Alzheimer's Association, 2014). Based on these figures, one could estimate that in 2014 there were 6.5 million to 8.7 million Americans with dementia. More than 15 million Americans, mostly family members, provide unpaid care to these individuals (Alzheimer's Association). Due primarily to the aging of the U.S. population, the prevalence of Alzheimer's disease and other dementias is projected to triple by midcentury.

The costs of care for people with Alzheimer's and related dementias are high for all payers, including Medicare, Medicaid, other public programs, private insurers, and individuals with dementia and their families (Bharmal et al., 2012; Bynum et al., 2004; Fortinsky, Fenster, & Judge, 2004; Hurd, Martorell, Delavande, Mullen, & Langa, 2013; Langa et al., 2004; Zhu et al., 2006). One recent analysis concluded that in 2010, total direct expenditures for dementia care were similar to total direct expenditures for heart disease and higher than total direct expenditures for cancer (Hurd et al.). The analysts also noted that these expenditures do not include the costs of "informal care, which are likely to be larger for dementia than for heart disease or cancer" (Hurd et al., p. 1331). Other analyses show that Medicare and Medicaid expenditures are considerably greater for individuals who have dementia plus other serious medical conditions than for individuals who have these other medical conditions but no dementia (Bynum et al.; Hill et al., 2002).

Dementia is an independent risk factor for nursing home admission in community-dwelling older adults, even when controlling for numerous comorbidities (Gaugler, Duval, Anderson, & Kane, 2007). Among community-dwelling older adults with dementia, functional disability and family caregiver physical and emotional strain are the most important predictors of

[1] The term *primary care provider* and the abbreviation *PCP* are used in this report to mean the physician, physician assistant, or nurse practitioner who provides, manages, and/or oversees individuals' primary medical care.

[2] The term *family caregiver* is used in this report to mean any relative, partner, friend, or neighbor who has a significant relationship with, and who provides a broad range of assistance for, an older adult with one or more chronic or disabling conditions (adapted from Feinberg, Reinhard, Houser, & Choula, 2011).

"...earlier diagnosis of Alzheimer's disease or other dementia will allow greater time for individuals and families affected by dementia to proactively plan in partnership with health and social care professionals..."

nursing home admission (Gaugler, Yu, Krichbaum, & Wyman, 2009). Physical and emotional burdens of providing help with activities of daily living, as well as the challenges of managing behavioral symptoms, such as agitation and resistance to care, place family caregivers at risk for depression, physical health problems, and admittance of their relative to a nursing home (Okura et al., 2011; Schulz & Beach, 1999; Spillman & Long, 2009). Thus, it is important to maintain the highest possible level of physical functioning and to reduce behavioral symptoms in people with dementia so that they can remain at home longer. In the context of this report, more systematic detection of cognitive impairment and, when appropriate, earlier diagnosis of Alzheimer's disease or other dementia will allow greater time for individuals and families affected by dementia to proactively plan in partnership with health and social care professionals the best ways to maximize their health and well-being as dementia-related symptoms arise and progress.

2. GSA WORKGROUP ON COGNITIVE IMPAIRMENT DETECTION AND EARLIER DIAGNOSIS: "HOW WAS THIS REPORT WRITTEN?"

In fall 2013, GSA established a multi-stakeholder workgroup with the expressed goals of (1) summarizing efforts currently underway by various national governmental and related organizations to identify evidence-based screening tools for mild cognitive impairment and (2) proposing an evidence-based pathway or guideline and process for securing inclusion of evidence-based screening tools in Medicare AWVs. This workgroup was charged with developing recommended actions by PCPs to increase their utilization of evidence-based screening tools for mild cognitive impairment and to identify barriers to adoption of those tools in AWVs. The workgroup also was charged with developing plans for a future interdisciplinary summit focused on both the assessment tools and the actions required to secure broad adoption of recommended steps to increase detection of cognitive impairment as a regular part of AWVs. The workgroup's long-term goal is to increase both detection of cognitive impairment and earlier diagnosis of dementia, leading to more appropriate post-diagnostic medical care and increased referrals for support services available in local communities and elsewhere that would measurably benefit people with dementia and their families.

An introductory and orientation meeting of the workgroup was held in December 2013, at which time it was agreed to expand membership for subsequent meetings. Full workgroup meetings were held in February, June, and September 2014. As of September 2014, members of the workgroup included representatives from the following stakeholder organizations: the Agency for Healthcare Research and Quality; the Alzheimer's Association (ex officio); the American Academy of Neurology; the American Association for Geriatric Psychiatry; the Centers for Disease Control and Prevention; the Centers for Medicare & Medicaid Services; Eli Lilly and Company (ex officio); the Health Resources and Services Administration; the Institute of Medicine, National Academy of Sciences; Leaders Engaged on Alzheimer's Disease (LEAD Coalition); the National Institute of Neurological Disorders and Stroke; the National Institute on Aging; and US Against Alzheimer's. Several members of the GSA workgroup also serve on the Advisory Council on Alzheimer's Research, Care, and Services, which provides advice to the U.S. Department of Health and Human Services about the National Plan to Address Alzheimer's Disease, and several are also members of the advisory committee for the National Quality Forum (NQF) project to set priorities for health care performance measurement for Alzheimer's disease and related dementias.

At its February 2014 meeting, two modifications were made to the workgroup's goals. The workgroup's initial charge focused on dementia *screening* tools but, in 2014, the U.S. Preventive Services Task Force (USPSTF) released its conclusion, similar to its previous position released in 2003, that "current evidence is insufficient to assess the balance of benefits and harms of screening for cognitive impairment" (Moyer, 2014, p. 791). In response to the USPSTF decision, the GSA workgroup revised its goal from identifying evidence-based assessment tools to *screen* for cognitive impairment in all older adults to identifying evidence-based assessment tools to *detect* cognitive impairment during the Medicare AWV in individuals who have signs and symptoms of cognitive impairment. Second, the workgroup originally used the terminology *mild cognitive impairment* to denote early, less severe impairment as opposed to frank dementia. Because mild cognitive impairment now carries diagnostic guidelines, the workgroup agreed to eliminate the term *mild* and to adopt the term *cognitive impairment* for purposes of achieving its goals and charge.

These two changes resulted in a revised workgroup name: GSA Workgroup on Cognitive Impairment Detection and Earlier Diagnosis. Based on proceedings from workgroup meetings and a selective review of published studies related to the workgroup's goals, this report summarizes the workgroup's recommendations and suggests ways to disseminate and implement recommendations to the maximum degree possible.

3. BACKGROUND ISSUES TO THE GSA WORKGROUP'S CHARGE: "WHAT IS THE CONTEXT?"

a. Gaps and Barriers in Detection of Cognitive Impairment and Diagnosis of Dementia

Although some (and perhaps many) PCPs recognize cognitive impairment in some or most of their older patients, findings from numerous studies indicate that cognitive impairment is not detected in substantial proportions of older primary care patients who have the condition (Boise, Neal, & Kaye, 2004; Boise et al. 2010; Borson, Scanlan, Watanabe, Tu, & Lessig, 2006; Chodesh et al., 2004; Ganguli et al., 2004; McCarten, Anderson, Kuskowski, McPherson, & Borson, 2012). These studies compare research-based findings of cognitive impairment in study subjects with documentation about cognitive impairment or dementia in the subjects' primary care medical records. PCPs could certainly be aware of cognitive impairment in some of their older patients but choose not to document the condition in the person's medical record. In fact, one study found that PCPs were aware of cognitive impairment in 44% of their patients who had the condition but only documented the condition in one quarter of those patients (Chodesh et al.). These findings suggest that the available figures for the proportion of older people with undetected cognitive impairment probably include not only people for whom PCPs have not detected the condition but also people for whom PCPs have detected the condition but chose not to document it in the patients' medical records.

As they have for cognitive impairment, many studies have found that dementia is undiagnosed in large proportions of primary care patients who have the condition (Boustani et al., 2005; McCarten et al., 2012; Valcour, Masaki, Curb, & Blanchette, 2000; Wilkins et al., 2007). A recent systematic review found that, on average, only 49% of primary care patients with diagnosable dementia had actually received a diagnosis (Bradford, Kunik, Schulz, Williams, & Singh, 2009). As with cognitive impairment, it is possible that some PCPs diagnose dementia in some of their patients but do not document the diagnosis in the patients' medical records. The proportions of undetected versus detected but undocumented cognitive impairment and dementia across primary care settings are not known.

The extent to which cognitive impairment and dementia are detected, diagnosed, and documented in patients' medical records varies by race and ethnicity. In the United States, African Americans and Hispanics are more likely than non-Hispanic whites to have cognitive impairment and dementia (Gurland et al., 1999; Lopez et al., 2003; Potter et al., 2009). Despite this higher prevalence, however, African Americans and Hispanics with dementia are, on average, less likely than non-Hispanic whites to have been diagnosed with the condition (Clark et al., 2005; Fitten, Ortiz, & Ponton, 2001). Moreover, African Americans and Hispanics with dementia often experience a longer delay between their family members' initial awareness of signs and symptoms of dementia and receipt of a diagnosis (Clark et al.; Connell, Roberts, McLaughlin, & Carpenter, 2009; Dilworth-Anderson, Hendrie, Manly, Khachaturian, & Fazio, 2008; Fitten et al.).

PCPs face a wide array of barriers to dementia diagnosis. Table 1 lists frequently noted barriers. Many dementia care experts and advocates believe that lack of routine assessment to detect cognitive impairment in primary care settings is another, and perhaps one of the most important barriers to dementia diagnosis in primary care (Ashford et al., 2006; Holsinger, Deveau, Boustani, & Williams, 2007; Larson, 1998).

Although a dementia diagnosis is not a message anyone hopes to hear, earlier

diagnosis of dementia can result in numerous possible benefits for people who have the condition and their families. Table 2 lists frequently noted benefits. The benefits are worded primarily from the perspective of individuals with dementia and their families, but some of the benefits related to improvements in ongoing medical management and health outcomes are also important from the perspective of the PCP.

The GSA workgroup acknowledged the importance of considering and giving equal attention to the perspectives of the person with dementia, the family caregiver, and the PCP throughout the process of cognitive impairment detection, diagnosis, and post-diagnosis referrals. This acknowledgement reflects the health care triad perspective in dementia care (Fortinsky, 2001) and represents a fruitful way to move forward by engaging all stakeholders in addressing barriers and filling gaps to achieve more systematic detection of cognitive impairment and earlier diagnosis of dementia.

b. Medicare Annual Wellness Visit

The Patient Protection and Affordable Care Act (ACA) of 2010 established the AWV as a new Part B benefit for Medicare beneficiaries. The law lists seven components of the AWV: (1) establishment of the individual's medical and family history, (2) a list of current medical care providers, (3) measurement of height, weight, and blood pressure, as well as other routine measurements, (4) detection of any cognitive impairment, (5) establishment of a schedule for future screenings and a list of needed preventive services, (6) personalized health advice and referrals for health education, and (7) other elements determined appropriate (ACA, 2010, pp. 1154–1156). Regulations to implement the new AWV benefit define *detection of any cognitive impairment* as "assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers or others" ("Annual Wellness Visits," 2010, p. 73613). After the first AWV, subsequent AWVs are required to include detection of cognitive impairment and all of the other mandated components of the first AWV except review of functional ability, level of safety, and risk for depression.

c. National Efforts to Provide Guidance for the Detection of Cognitive Impairment

Many dementia care experts and organizations that represent individuals with dementia, their families, and other care providers urged the Centers for Medicare & Medicaid Services (CMS) to issue regulations requiring providers to use a standardized assessment tool for detection of cognitive impairment,

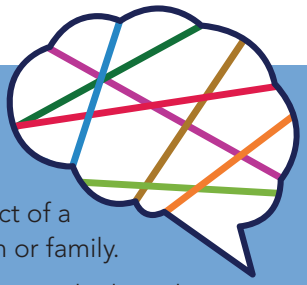


Table 1. Barriers to PCP Diagnosis of Dementia

Brief time for office visits.

Need to focus office time on diagnosis and treatment of the person's other physical health problems.

Inadequate diagnostic skills.

Concerns about the risk of misdiagnosis.

Limited availability of specialists to help with diagnosis.

Reluctance to refer the person or family to a specialist for diagnosis.

Worry that diagnosis will result in increased demand for limited resources, including physician time for communicating with and supporting family members.

Ambivalence about the value of diagnosis.

Belief that the symptoms are just normal aging.

Belief that the person or family doesn't want to know.

Concerns about the negative effect of a dementia diagnosis on the person or family.

Uncertainty about whether and how to disclose the diagnosis to the person or family.

Difficulty explaining or discussing dementia with the person or family.

Perceived lack of effective drug treatments.

Lack of awareness about nondrug treatments and community services and supports that have been shown to benefit people with dementia and their families.

Reluctance to acknowledge dementia in patients who are friends, neighbors, or members of the same religious or social group.

Low reimbursement for diagnosis.

Sources: Boise, Camicioli, Morgan, Rose, & Congleton, 1999; Boise et al., 2010; Bradford, Kunik, Schulz, Williams, & Singh, 2009; Fortinsky, Leighton, & Wasson, 1995; Fortinsky & Wasson, 1997; Hinton et al., 2007.

Table 2. Potential Benefits of Early Diagnosis of Dementia

Early diagnosis of dementia allows the person with the condition and his or her family and significant others to understand what is causing any observed decline in the person's cognitive and other abilities. It names the problem, eliminates the need for further searching to obtain a diagnosis, and validates concerns that have usually been present before a diagnosis is made.

If an early diagnostic evaluation shows that the person does not have dementia, the person and family are able to seek other causes for the person's cognitive decline, some of which may be partially or completely reversible with treatment.

Early diagnosis of dementia allows the person with the condition and his or her family and significant others to have important conversations about the person's wishes for his or her future care. The person with dementia has an opportunity to address legal and financial matters, designate a surrogate decision maker, and express preferences about future medical treatment and living arrangements while he or she still has decision-making capacity. This early planning can help to avoid crisis situations later on, when the person is no longer capable of expressing preferences or making decisions for himself or herself.

Early diagnosis of dementia allows the person with the condition and his or her family to think about and plan ways to avoid significant risks that are associated with cognitive decline for some people with dementia. These risks include financial losses due to reduced financial decision-making capacity and susceptibility to scams; accidents and injuries to the person with dementia or others due to unsafe use of tools, appliances, or guns; continuing to drive when the person is no longer capable of driving safely; and wandering and getting lost.

Early diagnosis allows the person with dementia and his or her family and significant others to benefit from dementia-specific support groups and other counseling, peer mentoring, disease education, socialization, exercise, and recreation programs that may be available in their community.

The currently available medications for Alzheimer's disease cannot prevent, cure, or delay the onset or progression of the disease, but they do help to reduce cognitive and other symptoms in some people with Alzheimer's for some time. Early diagnosis allows the person with dementia caused by Alzheimer's disease and his or her family to consider whether to try one or more of these medications.

Early diagnosis allows the person with dementia to decide whether to participate in research on new medications to prevent, cure, or delay the onset or progression of Alzheimer's and other diseases and conditions that cause dementia.

Early diagnosis of dementia allows family members to benefit from training about how to manage difficult caregiving issues, including dementia-related behavioral symptoms, and counseling and support to maintain their own health and reduce stress.

Early diagnosis can lead to more appropriate medical care and better health outcomes for the person with dementia. Without a diagnosis, people with dementia are more likely to receive medications for their other acute or chronic medical conditions that can worsen their cognitive functioning. In addition, people with dementia may be unable to report physical health symptoms accurately, comply with medical treatment recommendations, or take medications as prescribed. In the absence of a dementia diagnosis, PCPs, physician specialists, and other health care providers may not question a patient's reports about symptoms of coexisting medical conditions and compliance with recommended treatments, especially in the early stages of the patient's dementia. As a result, they may not be able to manage the patient's coexisting conditions effectively, resulting in potentially preventable worsening of the person's health and avoidable hospitalizations and emergency department visits.

and some also urged CMS to require the use of one or more specified tools. CMS regulations do give some discretion to PCPs to choose an appropriate tool, but to provide further guidance CMS requested suggestions from the National Institute on Aging (NIA) regarding evidence-based instruments that could be used by PCPs for detection of cognitive impairment during the AWV. The NIA formed an internal working group and convened three external meetings to solicit input from other federal agencies, assessment experts, clinicians, and other stakeholders. The NIA working group reviewed more than 130 peer-reviewed published assessment tools, developed a set of criteria they considered essential to detection of cognitive impairment in the primary care setting, and applied these criteria to the large listing of assessment tools they reviewed.

The criteria identified by the NIA working group were as follows:

- Less than or equal to 5 minutes to administer
- Free of charge with simple access
- Applicable to the Medicare population
- Designed to assess age-related cognitive impairment
- Must assess memory plus at least one other cognitive domain
- Validated in a U.S. community-based sample or primary care settings
- Post-validation used in United States between 2001 and 2011

The NIA has also posted online a searchable database of 116 instruments to detect cognitive impairment in older adults for use in outpatient practice or community studies (NIA, n.d.), and recently released Assessing Cognitive Impairment in Older Patients: A Quick Guide for Primary Care Physicians (NIA, 2014).

Concurrent with the NIA working group activities, the Alzheimer's Association convened a group of experts to provide guidance for primary care physicians about cognitive assessment during the AWV and further testing or referrals that may be needed (Cordell et al., 2013). The Association's Medicare Detection of Cognitive Impairment Workgroup developed principles to guide its work and recommended five brief assessment tools based on the principles.[i] The five brief assessment tools are shown in a later section of this report. The Alzheimer's Association workgroup also developed an algorithm showing recommended steps in the process of cognitive impairment detection and diagnostic evaluation.

STEP 1: Kickstart the cognition conversation

STEP 2: Assess if symptomatic

STEP 3: Evaluate with full diagnostic workup if cognitive impairment detected

STEP 4: Refer to community resources and clinical trials, depending on the diagnosis

Another ongoing national initiative that is relevant to the GSA workgroup's efforts is the Centers for Disease Control and Prevention (CDC) Healthy Brain Initiative. As part of this initiative, the Alzheimer's Association and the CDC recently released a document, *The Public Health Road Map for State and National Partnerships, 2013–2018*, presenting actions that state and local public health agencies and their partners can take to promote cognitive functioning, address cognitive impairment in community-living individuals, and support family caregivers (Alzheimer's Association & CDC, 2013). The document does not identify assessment tools to detect cognitive impairment or specific processes for earlier diagnosis of dementia. One of the recommended actions, however, is to "support continuing education efforts that improve health care providers' ability to recognize early signs of dementia, including Alzheimer's disease" (Alzheimer's Association & CDC, p. 36). Another recommended action is to "educate health care providers about evidence-based cognitive assessment tools that could be administered in such settings as physicians' offices, clinics, emergency rooms, and acute care hospitals' admission offices" (Alzheimer's Association & CDC, p. 36).

A final national initiative that is relevant to the GSA workgroup's efforts is a federally funded NQF project to set priorities for health care performance measurement for Alzheimer's disease and related dementias. The NQF final report, released in October 2014, does not identify assessment tools to detect cognitive impairment or a specific process for earlier diagnosis of dementia. It does, however, acknowledge the importance of detection of cognitive impairment and states, "The benefit of improved diagnostic processes and accompanying quality measures cannot be realized if the first step along that pathway (i.e., detection) is not addressed in a timely manner" (National Quality Forum, 2014, p. 26).

4. WORKGROUP RECOMMENDATIONS: "WHAT TO DO?"

a. Flow Diagram Framing Four-Step Process Endorsed by Workgroup

Figure 1 provides a flow diagram from the perspective of Medicare beneficiaries and their families that illustrates the aspirational process for achieving increased detection of cognitive impairment and shows how increased detection leads to earlier and optimal diagnostic evaluation, referral to post-diagnosis support and educational services in the community, and ultimately to improved health-related outcomes and

well-being for Medicare beneficiaries with diagnosed dementia and their families. The four steps endorsed by the GSA workgroup can be summarized by the following rubric:

STEP 1: **K**ickstart the cognition conversation
STEP 2: **A**ssess if symptomatic
STEP 3: **E**valuate with full diagnostic workup if cognitive impairment detected
STEP 4: **R**efer to community resources and clinical trials, depending on the diagnosis

Recommended steps and associated commentary in this section of the report are organized according to the four-step process illustrated in Figure 1 and encapsulated in the acronym KAER. Steps 1 and 2 (K and A) are discussed in greater detail in this report because they are directly related to the original goals and charge of the GSA workgroup.

Given the GSA workgroup's goals and charge, the intended starting point for Medicare beneficiaries is an AWV with their PCP. The workgroup recognizes, however, that Medicare beneficiaries and their family members, friends, and other caregivers might report concerns about the person's memory or cognition during any PCP visit. Likewise, a PCP could recognize that the Medicare beneficiary demonstrates clinical signs and symptoms of cognitive impairment during any office visit. In such instances, PCP actions would begin at Step 2 in the flow depicted in Figure 1.

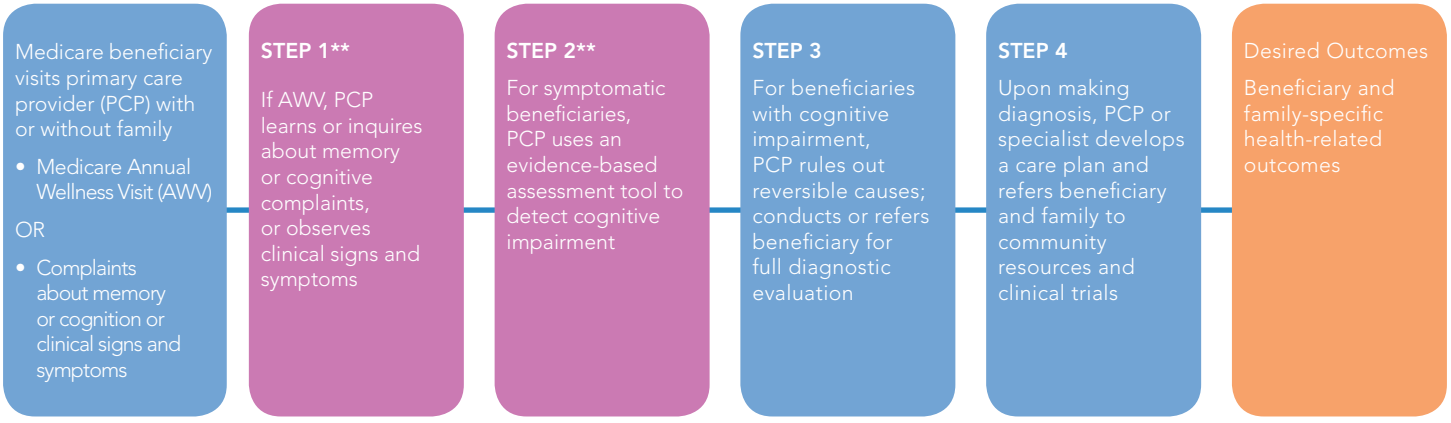
It is also important to note that the GSA workgroup's recommendations focus specifically on the role of PCPs in detecting cognitive impairment in primary care settings. Although the workgroup recognizes that increased detection of cognitive impairment is extremely important in other settings, such as emergency departments, hospitals, nursing home, and Medicare beneficiaries' homes, these care settings are beyond the scope of this workgroup's charge.

b. STEP 1—Kickstart Cognition Conversation

- During the Medicare AWV, PCPs should routinely ask beneficiaries about any noticeable changes in memory or cognition that have occurred since previous office visits. Additionally, PCPs should use their clinical judgment and observational skills to determine whether any changes in memory or cognition since previous encounters with beneficiaries are noticeable during the Medicare AWV.

To increase detection of cognitive impairment and promote earlier diagnosis of dementia in the Medicare population, the GSA workgroup strongly endorses that PCPs use the Medicare AWV as an annual opportunity to kickstart—that is, to initiate and continue—a conversation with beneficiaries and their families about memory-related signs and symptoms that might develop in older adulthood. It is quite clear from the studies reviewed earlier in this report on barriers to cognitive impairment detection that there are many reasons why PCPs might be reluctant to kickstart this conversation; similarly, beneficiaries and their loved ones may be reluctant to raise memory-related concerns with PCPs due to fear and stigma often associated with dementia. Nevertheless, a frank yet sensitive discussion initiated by the PCP during the Medicare AWV about the importance of brain health and early investigation of memory-related complaints or concerns is a highly appropriate first step to initiate

Figure 1. Medicare Beneficiary and Family Flow to Promote Cognitive Impairment Detection and Earlier Diagnosis of Dementia*



*4-Step Process—STEP 1: **Kickstart** cognition conversation; STEP 2: **Assess** if symptomatic; STEP 3: **Evaluate** with full diagnostic workup if cognitive impairment detected; STEP 4: **Refer** to community resources and clinical trials.

**STEP 1 and STEP 2 represent the GSA workgroup's original charge.

the cognition conversation. This essential first step might open the way for beneficiaries or others attending the office visit to reveal potential concerns. This approach is completely consistent with the definition of *detection of any cognitive impairment* in the regulation that created the Medicare AWV: "assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers or others" ("Annual Wellness Visits," 2010, p. 73613).

GSA workgroup members discussed extensively whether to endorse the approach of identifying beneficiaries who might be at risk for dementia during the Medicare AWV and initiating the use of a cognitive detection assessment tool (Step 2) for these individuals. However, due to a lack of conclusive scientific evidence that specific medical conditions or functional limitations are inevitably linked to the development of any type of dementia, the workgroup agreed not to endorse any specific risk factors for dementia that would automatically trigger the need for cognitive detection assessment.

However, the GSA workgroup strongly believes that PCPs are in a uniquely important position during the Medicare AWV to kickstart the cognition conversation. As such, PCPs can draw from recent scientific evidence about clinical and functional factors found to be significantly associated with Alzheimer's disease and related dementias in population studies to start this important conversation with their older patients and their families. Barnes and colleagues (2014) analyzed data from four national studies of U.S. older adults to build an algorithm—a dementia screening indicator—containing seven clinical and functional factors found in these studies to be associated with increased likelihood of having dementia. These factors, listed from most to least strongly associated with presence of dementia across the four studies, are as follows:

- Requires assistance with money/finances and/or medication administration
- Educational attainment less than 12 years
- Body mass index less than 18.5
- Depressive symptoms
- History of stroke
- Diabetes mellitus
- Age

The algorithm for this dementia screening indicator assigns points to each risk factor based on the strength of its association with dementia in the four studies. Barnes and colleagues (2014) recommended that individuals exceeding a threshold score should be tested with an evidence-based assessment tool to detect cognitive impairment.

The GSA workgroup is unaware of any clinical settings in which this algorithm and scoring system have been used to identify patients for cognitive impairment detection assessment, and therefore believes it is premature to endorse using this approach in clinical practice. However, the GSA workgroup believes that PCPs could use these findings to give higher priority to kickstarting the cognitive conversation during the Medicare AWV with patients with one or more known clinical and functional conditions on the list. Regarding age, the GSA workgroup concluded that no age threshold should be used in its own right if none of the other conditions on the list are present.

GSA workgroup members also discussed several additional clinical and functional factors that PCPs might use to place patients at higher priority for kickstarting the cognition conversations. Factors discussed by the workgroup members included falls and gait disorders, need for assistance with other daily activities that are not included in the Barnes criteria, adverse events resulting from medication administration errors, and hearing loss. These additional factors discussed by the GSA workgroup members are not known to cause dementia but rather have been shown to be associated with dementia. The extensive existing research on the relationship of falls and gait disorders, on the one hand, and cognitive impairment and dementia, on the other hand, shows that falls and gait disorders are often signs of mild cognitive impairment and very early Alzheimer's or other dementias (Alexander & Hausdorff, 2008; Fitzpatrick et al., 2007; Herman, Mirelman, Giladi, Schweiger, & Hausdorff, 2010; Stark et al., 2013; Verghese et al., 2008). Falls and gait disorders are also common in people with moderate and late-stage dementia (Allen, Ballard, Burn, & Kenny, 2005; Boise et al., 2004; Padubidri et al., 2014; Taylor et al., 2014). As a result of this epidemiological evidence in the published literature, when falls and gait disorders occur in primary care patients, PCPs could use these events and disorders as an entrée to engage patients in a conversation about the importance of monitoring cognitive health.

As a practical matter, it is likely that data reflecting clinical and functional factors associated with dementia discussed by the GSA workgroup are readily accessible in many primary care practices and clinics. The Alzheimer's Association Medicare Detection of Cognitive Impairment workgroup recommended that PCPs could use information from the health risk assessment (HRA) that is another component of the AWV to identify individuals who should be tested with a brief assessment tool to detect cognitive impairment (Cordell et al., 2013). CMS does not require physicians to use a specific HRA form for the AWV, but six components of the required HRA have been specified (76 FR 73470, Nov. 28, 2011).[ii] Some of the factors identified by Barnes and colleagues (2014) and the GSA workgroup are included in the specified components—for example, depression and ability to handle finances. PCP offices and clinics and

Candidate Assessment Tools Considered by the GSA Workgroup

	NIA Working Group	Alzheimer's Association Workgroup
Ascertain Dementia (AD8)	**X**	**X**
Brief Alzheimer's Screen	X	
GPCOG for use with the patient		X
GPCOG for use with an informant		X
Memory Impairment Screen		X
Mental Status Questionnaire	X	
Mini-Cog	**X**	**X**
Short Blessed Test	X	
Short IQCODE for use with an informant		X
Short Portable Mental Status Questionnaire	X	
Short Test of Mental Status	X	
Six-Item Screener	X	

electronic health records in larger health systems are also likely to include many of the factors identified by Barnes and colleagues and the GSA workgroup.

Finally, it is worth reiterating that the GSA workgroup devoted considerable time to discussing whether to endorse universal screening for cognitive impairment in the context of the Medicare AWV. Once the USPSTF report that did not recommend universal screening for cognitive impairment was released, in the midst of the GSA workgroup's deliberations, workgroup members agreed to abide by these USPSTF conclusions (Moyer, 2014).

c. STEP 2—Assess if Symptomatic

- As a result of Step 1 activities, PCPs should routinely use an evidence-based assessment tool to detect cognitive impairment for three types of beneficiaries identified at the Medicare AWV:
  - Those who report concerns about their memory or other cognitive abilities.
  - Those whose family members, friends, or other caregivers report concerns about the person's memory or other cognitive abilities.
  - Those with observable clinical signs and symptoms of cognitive impairment.
- PCPs should document results of the assessment process in the person's medical record. The specific tool used and the person's score should also be documented. If cognitive impairment is not assessed, PCPs should note why—such as no complaints or clinical signs and symptoms as a result of Step 1 activities, or symptomatic patient refused to be assessed.

The GSA workgroup endorses use of a cognitive impairment detection tool from a menu of tools having the following properties: (1) can be administered in 5 minutes or less, (2) widely available free of charge, (3) designed to assess age-related cognitive impairment, (4) assesses at least memory and one other cognitive domain, (5) validated in primary care or community-based samples in the United States, (6) easily administered by medical staff members who are not physicians, and (7) relatively free from educational, language, and/or cultural bias.

This workgroup endorsement combines properties of assessment tools consistent with guiding principles established by the Alzheimer's Association workgroup in its systematic reviews (Cordell et al., 2013), and properties consistent with criteria established by the NIA internal working group that examined an extensive list of tools.

In October 2012, CMS shared the NIA report to CMS that was a final summary of the NIA internal working group review of cognitive impairment detection tools (Ling, 2012). The report included a list of eight brief assessment tools that match the criteria identified by the NIA working group:

As discussed earlier in this report, the Alzheimer's Association Medicare Detection of Cognitive Impairment Workgroup developed principles to guide its work and recommended five brief assessment tools based on these principles.[i]

GSA workgroup members acknowledged that there is no perfect tool; however, by endorsing the use of a tool chosen from either of these lists, the workgroup offers a limited number of assessment tools for detection of cognitive impairment that are widely available, free of charge, and fulfill clinically relevant and scientifically rigorous criteria. The GSA workgroup also acknowledged that the NIA has a searchable database of 116 published tools for use in primary care and other outpatient health care practice settings and community studies (NIA, n.d.).

Recognizing the logistical challenges of operating busy primary care practices on a daily basis, the GSA workgroup also suggested that PCPs select tools that integrate most smoothly into the workflow of their practices and meet the needs of their patient populations. The workgroup also acknowledged that other tools to detect cognitive impairment are under development, and expressed the hope that the field will continue to refine these tools based on careful field testing in studies using prospective cohort designs. Moreover, the workgroup noted the need for evidence-based tools

that more effectively address cultural and language-related diversity, low literacy, sensory impairments, and intellectual disabilities in the Medicare population.

d. STEP 3—Evaluate With Full Diagnostic Workup if Cognitive Impairment Detected

If, as a result of using an evidence-based assessment tool to detect cognitive impairment per Step 2, PCPs find that Medicare beneficiaries have cognitive impairment, then:

- PCPs should, at a minimum, rule out reversible, physiological causes of cognitive impairment per published clinical practice guidelines (e.g., thyroid or vitamin deficiency) by ordering appropriate laboratory tests.
- Qualified PCPs should conduct a full diagnostic evaluation per published clinical practice guidelines.
- PCPs unfamiliar with a full dementia diagnostic evaluation should refer patients with no evidence of reversible causes of cognitive impairment to an available clinical specialist or team (e.g., geriatrician, neurologist, geriatric psychiatrist, neuropsychologist, nurse practitioner with geropsychiatric expertise) for a full diagnostic evaluation per published clinical practice guidelines.

The GSA workgroup recommends that all Medicare beneficiaries who exceed threshold scores for cognitive impairment based on the cognitive assessment tools used in Step 2 undergo a full diagnostic evaluation. Numerous published clinical practice guidelines are available to PCPs and specialists to help them arrive at a differential diagnosis of Alzheimer's disease or other dementia (see, e.g., American Academy of Neurology, n.d.; American Psychological Association, 2012; Galvin & Sadowsky, 2012; Group Health Cooperative, 2012; McKhann et al., 2011; Milisen, Braes, & Foreman, 2012; Moore, Patterson, Lee, Vedel, & Bergman, 2014).

Workgroup members discussed the importance of distinguishing between detecting cognitive impairment and arriving at an accurate diagnosis of a specific type of dementia. Workgroup members recognize that published studies have shown that only modest proportions of primary care patients who are determined to have some degree of cognitive impairment based on a detection tool such as the Mini-Cog go on to have a full diagnostic workup (Boustani et al., 2005; Boustani, et al., 2006; Harris et al., 2010; McCarten, et al., 2012). Adopting the health care triad perspective, it is highly likely that reasons for the low rate of diagnostic evaluation include factors related to individuals with cognitive impairment, family members, and PCPs. Other factors discussed by the GSA workgroup included the lack of available specialists to conduct full diagnostic evaluations, as well as long waiting times for appointments with specialists, even in areas where they are available. Action steps expected to follow the release of this report

will include discussions of how all members of the health care triad can be engaged to help increase the rate of full diagnostic evaluation among individuals suspected to have cognitive impairment based on steps recommended in this report.

e. STEP 4—Refer to Community Resources and Clinical Trials

The GSA workgroup recommends that all Medicare beneficiaries who are determined to have a diagnosis of Alzheimer's disease or related dementia be referred to all appropriate and available community services to learn more about the disease process and how to prepare for the future with a dementia diagnosis.

- Workgroup members agreed that PCPs should initiate a care plan for patients with diagnosed dementia. This care plan should document how ongoing medical management of comorbidities will be done, how progression of dementia-related neuropsychiatric symptoms will be monitored, and how referrals will be made to community resources.
- Specific community resources should include the local Area Agency on Aging, the local chapter of the Alzheimer's Association, state Aging and Disability Resource Centers, and, as appropriate, organizations representing different causes of dementia, such as Parkinson's disease and frontotemporal dementia.
- More specific recommendations for this step are beyond the scope of this workgroup, but literature cited earlier in this report strongly suggests that community resource referrals are rarely made by PCPs for their patients with dementia.
- Action on this step is required if the full value of uptake of earlier steps and recommendations is to be realized and translated into positive health-related outcomes for patients and families.

5. DISSEMINATION OF ACTION STEPS: "WHAT NEXT?"

- GSA workgroup progress, preliminary recommendations, and different stakeholder viewpoints on workgroup goals and charge were presented at a symposium at the 2014 GSA Annual Scientific Meeting in November 2014 in Washington, D.C.
- Plans are underway to organize and convene a national summit for 2015 with key stakeholders to help implement workgroup-endorsed actions.
- Target audience for summit: all stakeholders that could reach and work in partnership with PCPs. Invitees will include the following:
    - Insurers (CMS and Medicare Advantage plans), organized

care arrangements (health systems that include PCP practice groups and/or Medicare Accountable Care Organizations), Medicare Quality Improvement Organizations.

- Professional physician and other PCP membership organizations (e.g., the American Academy of Family Practice, the American College of Physicians, the National Medical Association) and national organizations representing nurse practitioners and physician assistants.
- For Step 3 recommendations, specialists to whom PCPs would refer Medicare beneficiaries for diagnostic evaluation can be reached through professional membership organizations (e.g., the American Academy of Neurology, the American Association of Geriatric Psychiatry, the American Geriatrics Society, the American Psychological Association).
- For Step 4 recommendations, health and social care organizations that offer or advocate for in-home and community-based services for people with dementia and their families, including AARP, the Alliance for Aging Research, the Alzheimer's Association, the Alzheimer's Foundation of America, and the LEAD Coalition.
- Federal agencies, including the Agency for Community Living, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and the National Institutes of Health.
- National organizations representing pharmacists, nutritionists, social workers, and occupational therapists.
- Representatives from the different Hartford initiatives at GSA, including those with nurses and social workers, as well as other dementia and caregiver-related initiatives sponsored by GSA, plus change agents.
- The summit will be organized according to themes intended to facilitate improvement in all steps illustrated in Figure 1:
    - Health care triads.
    - Racial, ethnic, cultural, and linguistic diversity.
- Issues raised by the GSA workgroup, but for which no consensus was reached, will be addressed at the summit as well:
    - How to explain the AWV more clearly to providers and consumers so their expectations are consistent with the intent of the legislation and with each other.
    - How to incorporate cognitive detection tools and algorithms into electronic medical records.
    - Should a family caregiver assessment also be recommended for patients with verified cognitive impairment?
    - How to identify a source of support for people who do not have any family, or who routinely visit their PCP without any family members.
- The GSA workgroup discussed whether and how the full set of recommendations in this report might be tested for feasibility and fidelity by groups of PCPs and their local community partners in a defined geographic area. At the summit, time will be devoted to identifying one or more geographic areas where workgroup recommendations could be tested.

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END NOTES

[i] The principles used by the Alzheimer's Association Medicare Detection of Cognitive Impairment Workgroup to guide the development of recommendations for cognitive assessment, including recommended brief assessment tools for use in detecting cognitive impairment in the Annual Wellness Visit (AVW), are as follows (Cordell et al., 2013):

- Detection of cognitive impairment is a stepwise, iterative process.
- Informal observation alone by a physician is not sufficient (i.e., observation without a specific cognitive evaluation).
- Detection of cognitive impairment can be enhanced by specifically asking about changes in memory, language, and the ability to complete routine tasks.
- Although no single tool is recognized as the gold standard for detection of cognitive impairment, an initial structured assessment should provide either a baseline for cognitive surveillance or a trigger for further evaluation.
- Clinical staff can offer valuable observations of cognitive and functional changes in patients who are seen over time.
- Counseling before and after cognitive assessment is an essential component of any cognitive evaluation.
- Informants (e.g., family member, caregiver) can provide valuable information about the presence of a change in cognition.
- The AWV requires the completion of a health risk assessment (HRA) by the patient either before or during the visit. The HRA should be reviewed for any reported signs and symptoms indicative of possible dementia.
- The AWV will likely occur in a primary care setting. Tools for initial cognitive assessments should be brief (less than 5 minutes), appropriately validated, easily administered by nonphysician clinical staff, and available free of charge for use in a clinical setting.
- If further evaluation is indicated based on the results of the AWV, a more detailed evaluation of cognition should be scheduled for a follow-up visit in primary care or through referral to a specialist.

[ii] *Health risk assessment* means, for the purposes of this section, an evaluation tool that meets the following criteria:

i. Collects self-reported information about the beneficiary.
ii. Can be administered independently by the beneficiary or administered by a health professional prior to or as part of the AWV encounter.
iii. Is appropriately tailored to and takes into account the communication needs of underserved populations, individuals with limited English proficiency, and people with health literacy needs.
iv. Takes no more than 20 minutes to complete.
v. Addresses, at a minimum, the following topics:
   A. Demographic data, including but not limited to age, gender, race, and ethnicity.
   B. Self-assessment of health status, frailty, and physical functioning.
   C. Psychosocial risks, including but not limited to depression/life satisfaction, stress, anger, loneliness/social isolation, pain, and fatigue.
   D. Behavioral risks, including but not limited to tobacco use, physical activity, nutrition and oral health, alcohol consumption, sexual health, motor vehicle safety (seat belt use), and home safety.
   E. Activities of daily living (ADLs), including but not limited to dressing, feeding, toileting, grooming, physical ambulation (including balance/risk of falls), and bathing.
   F. Instrumental activities of daily living (IADLs), including but not limited to shopping, food preparation, using the telephone, housekeeping, laundry, mode of transportation, responsibility for own medications, and ability to handle finances.

COGNITIVE
IMPAIRMENT
DETECTION
& EARLIER
DIAGNOSIS