

# ADVISORY COUNCIL ON ALZHEIMER'S RESEARCH, CARE, AND SERVICES

Washington, DC and Virtual Meeting

**August 5, 2024**

## Advisory Council Members in Attendance

- *Non-Federal Members Present:* Adrienne Mims (Chair), Randall Bateman, Susan DeMarois, Keun Kim, Helen Bundy Medsger, John-Richard Pagan, Rhonda Williams
- *Federal Members Present:* Arlene Bierman, Agency for Healthcare Research and Quality (AHRQ); Bruce Finke, Indian Health Services (IHS), Sarah Fontaine, Department of Defense; Richard Hodes, National Institutes of Health/National Institute on Aging (NIH/NIA); Erin Long, Administration for Community Living (ACL); Tisamarie Sherry, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
- *Quorum present?* Yes
- *Advisory Council Designated Federal Officer:* Helen Lamont (ASPE)
- *Other Federal Representatives Present:* Amy Kelly (NIH/NIA), Ellen Blackwell, Centers for Medicare & Medicaid Services (CMS); Jolie Crowder (IHS); Scotte Hartronft, Department of Veterans Affairs; Alisa Etheredge, Centers for Disease Control and Prevention (CDC); Maria-Theresa Okafor (ASPE); Frank Shewmaker, NIH/National Institute of Neurological Disorders and Stroke (NINDS)

## General Proceedings

The Advisory Council on Alzheimer's Research, Care, and Services was convened for its third meeting of the year at 9:33 a.m. Eastern Standard Time in Washington, D.C., and virtually. Dr. Adrienne Mims, Advisory Council Chair welcomed meeting participants and reviewed the meeting agenda. The meeting was open to the public.

## Federal Updates

**Erin Long, ACL.** In July 2024, ACL's new Center for Dementia Respite Innovation announced \$4 million in grants to 21 community-based service providers to increase

availability of dementia-specific respite care. ACL's National Alzheimer's and Dementia Resource Center (NADRC) will host webinars on dementia training for Transportation Security Administration staff (August 12) and cognitive stimulation therapy (August 27). Recent webinars on brain health and risk reduction efforts in Puerto Rico and Virtual Dementia Tour program implementation in Tribal communities, and new training resources are available on NADRC's website. The Great Lakes Intertribal Council, has developed two videos on dementia experiences in Tribal communities.

**Arlene Bierman, AHRQ.** AHRQ released a strategic plan, *Advancing Health System Transformation to Optimize Health, Functional Status, and Well-being among Older Adults*; a Special Emphasis Notice on improving care of older adults; and a Notice of Intent (Notice of funding opportunity is forthcoming) to fund approximately 15 state-based health care collaboratives aimed at improving care, and national coordinating and evaluation centers. The implementation guide for AHRQ's eCare Plan app that supports care coordination across multiple electronic health record systems, has been approved and will be available shortly. The national person-centered care initiative is working to bring many stakeholder groups together to share innovations and accelerate change; a summit will be held in spring 2025.

**Tisamarie Sherry, ASPE.** Recent ASPE briefs were highlighted:

- *Changes in Ownership of Skilled Nursing Facilities from 2016 to 2021: Variations by Size, Occupancy Rate, Penalty Amount, and Type of Ownership*, examined publicly available CMS data to explore the relationship between skilled nursing facility ownership changes and care quality. The study found that medium-sized facilities with lower occupancy and higher rates of fines were more likely to experience ownership changes that are potentially disruptive to care quality.
- *Medicaid Home and Community-Based Services Section 1915(c) Waiver Policy Flexibilities During the COVID-19 Public Health Emergency: State Agency, Provider, and Consumer Experiences*, was based on interviews with state agencies and home and community-based services (HCBS) consumer and provider groups, seeking to understand their experiences with Medicaid waivers during the pandemic. ASPE will use the findings to better support states in providing long-term services and supports (LTSS) to people living with dementia (PLWD).

**Alisha Etheredge, CDC.** CDC and IHS are releasing the first publication providing estimates of dementia prevalence among American Indian and Alaskan Native populations. CDC shared many resources from funded partners. The American College of Preventative Medicine (ACPM) released a toolkit, *Community-Clinical Linkages to Promote Brain Health*, to help physicians educate patients about Alzheimer's disease and related dementias (AD/ADRD) and risk factors. ACPM developed two new courses for health care providers: *Improving Brain Health: A Practical Review of Dementia Risk Reduction Strategies* and *Heart Healthy is Brain Healthy: Cognitive Decline and Dementia Risk Reduction through Blood Pressure Control*. The American Medical Association, CDC, and Alzheimer's Association hosted a three-part webinar series, *Navigating Brain Health: Alzheimer's and Dementia*. The Alzheimer's Association has

released a new infographic on Alzheimer's and public health, and is accepting applications until September 26, 2024, for Healthy Brain Initiative (HBI) Road Map Strategists, a 9-month program that helps local health departments address cognitive health. The HBI Road Map for American Indian and Alaska Native Peoples Update will be released in November 2024.

BOLD Centers of Excellence activities include(d): a webinar series on social determinants of health (SDOH) and dementia risk and the release of three infographics and three videos on modifiable risk factors (BOLD Center of Excellence on Risk Reduction); sharing of the *Early Detection of Dementia Toolkit -- Health Systems* and a recorded webinar series (BOLD Center of Excellence on Early Detection); and offering a roundtable series on innovative state approaches to advancing dementia caregiving goals and introduction of a related toolkit, *Disseminating Evidence-Based Programs to Support Family Dementia Caregivers: The Role of Public Health* (BOLD Center of Excellence on Dementia Caregiving).

The USAgainstAlzheimer's Center for Brain Health Equity launched a nurse fellowship program and digital ad campaign to better serve Black and Latino communities. The University of Illinois-Chicago's HealthMatters program is partnering with the National Task Group on Intellectual Disabilities and Dementia Practices (NTG) to develop intellectual and developmental disability (IDD)-related training and technical assistance materials for GUIDE participants, supported by Special Olympics. BOLD and HBI grant recipients have released new field stories highlighting their work (available online).

**Ellen Blackwell, CMS.** Highlights from key CMS rules and related activities were discussed:

- 2025 Proposed Medicare Physician Fee Schedule: includes proposals for refinement of Caregiver Training Services including behavior management and modification training which may impact PLWD; a broad Request for Information to get input on Community Health Integration, Principal Illness Navigation, and SDOH Health Risk Assessment services; and Safety Planning for people at risk for mental health crisis. Public comments close September 9, 2024.
- The recently finalized 2025 regulation governing payments for hospitals includes an age friendly hospital measure.
- National Coverage Determination (NCD): Coverage with Evidence Development (CED) updates were highlighted -- Kisunla (donanemab) was Food and Drug Administration (FDA)-approved on July 2, 2024, and added to the CMS National Patient Registry. Three CED studies are currently under the NCD, with thousands of entries since July 2023.
- CMS continues ongoing work to reduce use of unnecessary anti-psychotic medications in nursing home settings; see CMS Care Compare website for details.

**Teresa Buracchio, FDA.** Kisunla received approval based on data from an 18-month Phase 3 trial of people with mild Alzheimer's disease or mild cognitive impairment (MCI). Amyloid related imaging abnormalities (ARIA), headache, and infusion-related

reactions were the most common side effects; ARIA was observed in 36% of subjects. Optimal dosing and length of treatment is still being studied; patients can consider cessation when amyloid positron emission tomography is reduced to minimal levels. Neurologic deficits that mimic an ischemic stroke are a newly identified risk. Treating clinicians need to be aware of this to avoid providing inappropriate treatment to patients with stroke-like symptoms.

**Bruce Finke, IHS.** IHS is reviewing 2024 grant applications for the Addressing Dementia in Indian Country: Models of Care program. Up to six grantees will be announced soon. The Indian Health Geriatric Scholars program is reviewing its third round of applicants. Sixteen nurses completed the first pilot year of the Geriatric Nurse Fellowship. The second round of pilot programs incorporating tools for dementia detection into oral health care practices has finished. IHS and CDC will release a report with baseline data on dementia prevalence among American Indian and Alaskan Native populations, based on IHS claims data.

**Richard Hodes, NIA.** The fiscal year (FY) 2026 Professional Judgement Budget was reviewed. A total of nearly \$4 billion is needed for FY2026 (approximately \$113 million more than the baseline estimate). The new *Alzheimer's and Related Dementias Progress Report* summarizes significant NIH-funded dementia research advances over the past year milestones towards the goals of the national plan (see <https://www.nia.nih.gov/research/milestones> for more information). The next NIH Alzheimer's Research Summit is September 23-25, 2024.

**Frank Shewmaker, NINDS.** In 2023, NINDS spent \$443.6M on AD/ADRD. Since 2015, NINDS has developed over 90 funding opportunities to address the priorities identified through ADRD summits and roundtables. Gene editing is one area of interest for future Alzheimer's disease treatment. NINDS has funded research on optimization for genome editing, which is examining an animal model of gene editing and reissuing a funding opportunity for gene editing in AD/ADRDs. NINDS has 21 AD/ADRD funding opportunities listed on the NINDS website.

## **Guiding an Improved Dementia Experience (GUIDE) Model: Participant Summary**

**Tonya Saffer, CMS**

The GUIDE Model launched on July 1, 2024, with 390 participants in 46 states, serving Medicare beneficiaries in all 50 states. Ninety-six participants are established programs, and 294 are new programs. Twenty-nine new programs are designated as Safety Net Providers and will receive a \$75,000 infrastructure payment to support development.

Most participants are physician group practices and clinics; 22% serve rural areas, and 41% serve low to medium-income diverse communities. Participants have estimated they will serve over 200,000 Medicare beneficiaries living with dementia. The goals of GUIDE are to improve quality of life for PLWD, reduce placement in facilities, and

reduce strain for caregivers. Participants will submit annual reports on progress toward health equity goals.

### ***Discussion***

- Dr. Mims asked about hospice organizations involvement in the model. Beneficiaries enrolled in hospice are not eligible for GUIDE, but many hospice providers deliver other palliative and respite services to PLWD and their caregivers. Hospice GUIDE participants will use their expertise in palliative care as part of their GUIDE program delivery.
- Roughly one-third of the Medicare population has a dementia diagnosis. The estimate of 200,000 people served through GUIDE is based on self-reported data on participants' GUIDE applications. Beneficiaries do have to consent to be part of the program.
- Medicare Advantage plans serve 50% of Medicare beneficiaries and are not eligible for GUIDE. CMS has informed these providers about GUIDE and reminded them they can offer supplemental benefits to PLWD. Members should share examples with ASPE of Medicare Advantage plans that deliver similar services.
- To measure reduced burden on caregivers, populations receiving the intervention will complete the Zarit Burden Scale, and the evaluation will compare these beneficiaries to a group of Medicare fee for service beneficiaries who are not participating in GUIDE.
- CMS will be sending letters next year to all beneficiaries with GUIDE in their area.

## **Clinical Care Subcommittee Presentations**

### ***“Improving Dementia Diagnoses among Minority Populations: 5-Cog Cognitive Detection Tool”***

***Joe Verghese, MD, MS, FRCPI, Montefiore-Einstein Center for the Aging Brain and Resnick Gerontology Center, Albert Einstein College of Medicine***

The 5-Cog is a cognitive battery and decision tree involving three tests in 5 minutes, designed to improve dementia care for older adults with memory concerns. It includes a picture-based memory screen adapted to the local population, test matching symbols to numbers, and timed walk. Community health workers (CHWs) or other non-clinicians can be trained to perform the 5-Cog. If the 5-Cog is positive, recommendations are available to the physician, including options to refer for further assessment.

A study of about 1,200 racially and educationally diverse patients found that use of the 5-Cog in a primary care setting resulted in a threefold increase in dementia care, including a five-fold increase in diagnosis of MCI and dementia by primary care physicians, an increase in laboratory and imaging tests, and an increase in specialist referrals. The 5-Cog did not impact new prescriptions for memory impairment,

hospitalizations, or emergency department use. Preliminary analysis suggests that costs were not prohibitive.

Currently, a 5-Cog 2.0 trial is underway that is examining issues of implementation more closely, including cost-effectiveness. As part of the 2.0 trial, the gait speed test has been replaced with questions about mobility and gait speed to further streamline administration.

### ***Discussion***

- Using CHWs can help with scaling of an intervention like the 5-Cog. Tools are also needed for following up on after care to ensure that primary care physicians refer to specialists, order the appropriate tests, and engage with social services.
- A question was asked about using the 5-Cog with younger patients rather than restricting to people aged 65 or older. The parameters were established partly in relation to the Medicare Annual Wellness Visit for people aged 65 and older. The positivity rate for people below 65 will be much lower, and other factors such as depression and anxiety can also cause symptoms related to dementia.
- Dr. Verghese considers the 5-Cog to be a brief cognitive screen, similar in length and complexity to the Mini-Cog.

### ***“Clinical Care Subcommittee Recommendations”***

***Adrienne Mims, MD, MPH, FAAFP, AGSF***

The draft [Clinical Care Subcommittee recommendations](#) address the following topics:

1. Reauthorization of and budget appropriations for NAPA for another 10 years.
2. Increased education resources for the public and health care providers.
3. Improve systems of clinical care.
4. Implement solutions to address the geriatric and gerontology workforce crisis.
5. PLWD and their unpaid caregivers to be integral parts of the care team.
6. Eliminating barriers to clinical care and LTSS for adults with young onset dementia.

## **Research Subcommittee Presentations**

### ***“Alzheimer’s Disease and Related Dementia: Late-Breaking Research Findings”***

***Jorge J. Llibre-Guerra, MD, MSc Washington University School of Medicine in St. Louis***

Findings from the 2024 Alzheimer’s Association International Conference and other research reports from the past year relate to four topics: (1) addressing risk factors and trends; (2) genetic insights; (3) emerging fluid biomarkers; and (4) prevention and treatment advances.

- About 45% of dementia cases could be prevented; the greatest benefit will come from addressing midlife risk factors. Population-based studies show that

dementia incidence has become stable or is decreasing in some countries while in other countries -- or specific ethnic groups within countries -- there are increases.

- Knowledge of the genetics of AD/ADRD has improved greatly in recent years, but is mainly based on non-Hispanic White populations. Some genes identified as increasing Alzheimer's risk, such as ApoE4, are not carried or expressed uniformly across populations. For example, Black Caribbean Hispanics are more likely than Whites to carry the APOEε4 gene variant, but the association between this genotype and dementia is weaker in those who self-identify as Black than in White populations.
- Blood biomarker tests are a promising area of development due to their ability to measure multiple proteins with a single sample, being faster and less expensive to collect than PET imaging or cerebrospinal fluid tests, and high accuracy. This will facilitate clinical trial recruitment. Most blood biomarker data comes from non-Hispanic White populations, but studies are being conducted on other populations.
- Potential prevention and treatment targets are many. Possible drug targets include amyloid beta; inflammation; vasculature; ApoE, lipids, and lipoprotein receptors; and neurotransmitter receptors. The recently approved drugs can delay progression and have shown that significant amyloid removal leads to a cognitive benefit, but do not replace the need for a cure.
- The Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) recently presented the first evidence of dementia prevention in an asymptomatic group. The trial used amyloid plaque-removing drugs in high-risk individuals with existing amyloid plaques; those treated for an average of 8 years showed a 50% decrease in risk of conversion to symptomatic dementia and dementia progression rate. DIAN-TU next will conduct a prevention trial, targeting individuals at risk who do not yet have amyloid plaques.
- The next 5 years are key for exploring tau therapies, including genetic therapies, clearing tau tangles, and using antibodies to prevent tau tangles. We need to better understand the right targets for tau, appropriate dosages, and best timing for treatment. We also need combination therapies that target both amyloid and tau.

### ***“Research Subcommittee Recommendations”***

***Randall Bateman, MD***

The draft [Research Subcommittee recommendations](#) address the following topics:

1. Increase federal research funds to meet NAPA aims.
2. Address critical scientific and clinical questions in the implementation of the first generation of disease-modifying treatments.
3. Implement research of active dementia care models to compare effectiveness.
4. Address health equity and the underrepresentation of diverse populations in research in AD/ADRD clinical trials.

5. Accelerate translation from scientific discovery to health impact.
6. Implement scientific and evidence-based evaluations of factors for decision-making.

## **LTSS Subcommittee Presentations**

### ***“The Dignity -- and Disruptions -- of Caregiving”***

***Susan DeMarois, Director, California Department of Aging***

According to the Alzheimer’s Association, over 11 million Americans provided an estimated 18.4 billion hours of unpaid dementia care in 2023. Most caregivers are women in middle age, with growing numbers of younger caregivers, and represent all races, ethnicities, languages, cultures, and sexual orientations. Caregiving can be meaningful and satisfying but can also negatively impact caregivers’ physical and mental health, finances, and work.

More than one-half of caregivers who responded to the Behavioral Risk Factor Surveillance System survey indicated that their own health is challenged. Fifty-nine percent report high to very high stress and are often isolated without assistance. Dementia caregivers spend twice as much as non-dementia caregivers on out-of-pocket care expenses. About 60% of caregivers work -- and leaving the workforce to provide care, if necessary, means loss of health insurance, career advancement, retirement income, and Social Security.

Caregivers often report lack of skills and knowledge to perform caregiving duties; many feel they did not have a choice in becoming a caregiver. Currently, federal agencies are supporting caregivers through: American Rescue Plan Act funding; the RAISE Family Caregiver Act; the National Strategy on Family Caregiving; ACL’s Older Adults Act final rule and reauthorization naming family caregivers as a specific target; the CMS physician fee schedule; and the CMS GUIDE model.

### ***“LTSS Subcommittee Recommendations”***

***Helen Bundy Medsger***

The draft [LTSS Subcommittee recommendations](#) address the following topics:

1. Reauthorize and provide Budget Appropriations for NAPA.
2. Expand Older Americans Act services and funding to help people of all ages living with AD/ADRD and their family caregivers.
3. Expand the availability of dementia-capable HCBS.
4. Define needs and expand LTSS to people living with young onset AD/ADRD and their families/caregivers.
5. Expand the availability LTSS tailored to high-risk populations.
6. Identify adults with a diagnosis of AD/ADRD living alone and develop strategies to address their LTSS needs.



7. Implement solutions to address the LTSS workforce crisis.
8. Expand awareness and engagement in the public and private sectors about AD/ADRD.
9. Provide funds to address the needs of older adults with dementia or cognitive impairment and experiencing homelessness.
10. Implement strategies that create the conditions for high-quality person-centered and strengths-based LTSS throughout the course of the disease.
11. Develop and implement systems and programs that support PLWD while incarcerated.

## **Risk Reduction Subcommittee Presentations**

### ***“Late-Breaking Risk Reduction Research Findings from the Alzheimer's Association International Conference”***

***Heather Snyder, PhD, Alzheimer's Association***

The Alzheimer's Association International Conference was held July 28-August 1, 2024. The Lancet Commission identified 14 modifiable risk factors that can reduce risk of dementia. Two factors are new -- HDL cholesterol and vision loss. Key factors in midlife include hearing loss, high HDL, depression, traumatic brain injury, physical inactivity, diabetes, smoking, hypertension, obesity, and excessive alcohol use. In later life, social isolation, air pollution, and vision loss are key modifiable risk factors. Many factors are interrelated, such as vision loss and social isolation; more research is needed to understand the interplay of these factors. Exposure to wildfire smoke is an increasing threat to brain health according to a 10-year study of more than 1 million people in California. Diet is a complex factor not included in the list of 14.

More research needs to establish whether risk factors identified by the Lancet Commission are causal. The SPRINT MIND study provides one example of a causal link: it demonstrated that intensive treatment of blood pressure, as compared to standard treatment, significantly reduces the risk of dementia.

### ***Discussion***

- Multi-component risk reduction trials are underway that will help inform integration of risk factor information into public health messaging. Communication strategies matter to clinical trial recruitment and public health interventions.
- Cardiovascular health has many of the same risk factors as dementia and has been promoted for decades. The risk factors are similar, but new knowledge about social messaging and social supports can guide public health communications and program design. Adrienne Mims added that for some caregivers, seeing the impact of dementia on their parents creates greater interest in the topic of prevention.
- Hearing and vision impairment are risk factors, but treatments often are not covered by insurance. The BOLD Center for Early Detection's manual for health

care providers has a wealth of information in its guidance to providers, including information on vision and hearing. House and Senate legislation providing Medicare coverage for dental, hearing, and vision benefits has not yet passed.

### **“Risk Reduction Subcommittee Recommendations”**

**Helen Lamont, PhD (for Joanne Pike, DrPH)**

The draft [Risk Reduction Subcommittee recommendations](#) address the following topics:

1. Prioritize risk factors, identify prevalence, and track progress toward addressing cognitive decline and dementia risk factors across the lifespan.
2. Accelerate public health and aging network action, particularly for communities or groups at greatest risk.
3. Identify and accelerate efforts to reduce risk and intervene early in primary clinical care.
4. Initiate and fund research to strengthen strategies for addressing risk factors.
5. Work with appropriate non-federal governmental entities and private sector organizations to improve brain health.
6. Establish a set of policies at the federal, state, and local level that will address risk factors, including SDOH, for cognitive decline and dementia.

## **VOTING AND ADOPTION OF RECOMMENDATIONS**

The non-federal Advisory Council members present voted unanimously to approve the subcommittee recommendations for clinical care, research, LTSS, and risk reduction.

### **Public Comments**

- **Michael Ellenbogen** noted that the CMS-1808-p proposed rule falls short of helping people with cognitive issues. He recommends screening all admitted hospital patients over age 65 (and younger patients at risk) for cognitive issues, including dementia and delirium; improving ways to make hospital staff aware that a patient has likely cognitive issues; and training hospital staff on appropriate care for patients with cognitive impairment. He has formed a new company of dementia training professionals ready to train hospital staff with evidence-based programs.
- **Adina Lasser**, Public Policy Manager at the Alliance for Aging Research, shared three recommendations. First, the Federal Government needs to prioritize screening for cognitive impairment as an A or B recommendation with the U.S. Preventative Services Taskforce (USPSTF); the USPSTF has maintained an “insufficient” recommendation since 1996 despite extensive research showing evidence for early screening. Second, CMS should be required to provide data from its extracellular domain for monoclonal antibody treatments. Third, CMS uses a poorly targeted quality measure for anti-psychotic use in patients with

neuropsychiatric symptoms of AD/ADRD. These measures penalize smaller rural facilities and facilities that focus on treating complex cases of neurocognitive decline and do not sufficiently distinguish appropriate and inappropriate use of the medications. CMS has not disclosed data on how many residents are involuntarily discharged from nursing homes due to these policies or the number of potential residents denied admission.

- **Nancy Murray**, Board Member of the NTG, noted that the NTG recently received a grant from the Special Olympics that will train GUIDE program care navigators to address barriers to care experienced by people with IDD. Murray has three adult children with Down syndrome, one of whom was recently diagnosed with Alzheimer's disease. People with Down syndrome have much higher prevalence of Alzheimer's disease. About 60% of people with IDD who receive Medicaid-funded services live with their families. Their caregivers experience emotional, physical, and financial strain, particularly older caregivers. She asks that adults with IDD be included in clinical trials for medications that treat Alzheimer's disease.
- **Ryan Rotundo**, Director of National Programs, National Down Syndrome Society (NDSS). His sister with Down syndrome celebrated her 40th birthday recently, which also brought concerns about risks that she faces as she ages. He noted again the increased risk of dementia for individuals with Down syndrome. He applauds the robust inclusion of Down syndrome in the Advisory Council draft recommendations. NDSS is committed to working with the Council to see these recommendations implemented. He asks for continued advocacy to move these recommendations forward.

## Concluding Remarks

Dr. Adrienne Mims noted that the Council's next meeting will be held on October 21, 2024, and will focus on clinical care.

The meeting adjourned at 4:05 p.m.

Minutes submitted by Helen Lamont (ASPE).

All presentation handouts are available at <https://aspe.hhs.gov/collaborations-committees-advisory-groups/napa/napa-advisory-council/napa-advisory-council-meetings>.

Final Recommendations are available at <https://aspe.hhs.gov/collaborations-committees-advisory-groups/napa/napa-documents/napa-recommendations>.