

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

Virtual Meeting

January 24, 2022

Advisory Council Members in Attendance

- *Non-Federal Members Present:* Cynthia Carlsson (Chair), Randall Bateman, Venoreen Browne-Boatswain, Matthew Janicki, Keun Kim, Helen Bundy Medsger, Adrienne Mims, Carrie Molke, Joe Montminy, Maria Ortega, Joanne Pike, Rhonda Williams
- *Federal Members Present:* Arlene Bierman (Agency for Healthcare Research and Quality, AHRQ), Bruce Finke (Indian Health Services, IHS), Richard Hodes (National Institutes of Health, NIH), Shari Ling (Centers for Medicare & Medicaid Services, CMS), Erin Long (Administration for Community Living, ACL), Lisa McGuire (Centers for Disease Control and Prevention, CDC), Deborah Olster (National Science Foundation, NSF), Tisamarie Sherry (Department of Health and Human Services, HHS; Office of the Assistant Secretary for Planning and Evaluation, ASPE), Joan Weiss (Health Resources and Services Administration, HRSA)
- *Quorum present?* Yes
- *Advisory Council Designated Federal Officer:* Helen Lamont (ASPE)

General Proceedings

Chair Cynthia Carlsson called the meeting to order at 12 p.m. Eastern Daylight Time. She welcomed meeting participants and reminded participants that the central topic would be clinical care.

Federal Updates

- Shari Ling presented **CMS** updates. On January 11, 2022, CMS released a National Coverage Determination that proposed coverage for the Food and Drug Administration (FDA)-approved monoclonal antibodies that target amyloid for treatment of Alzheimer's disease through coverage with evidence development (CED). The memorandum is available online. CMS will accept public comments

through February 10, 2022. CMS will announce its final decision by April 11, 2022.

- CMS also provides billing codes for screening and diagnosis, and information about how to deliver and bill for these services. CMS is working to improve behavioral health in nursing homes through public/private partnerships and tracking use of antipsychotic drugs in nursing homes. CMS provided guidance for nursing home visitation that emphasizes permitting visitation at all times while adhering to core principles of infection prevention.
- Arlene Bierman provided **AHRQ** updates. AHRQ is collaborating with the National Institute of Diabetes, Digestive, and Kidney Disease to build capacity for pragmatic patient outcomes-centered research (PCOR) by developing an interoperable electronic care plan that facilitates aggregating and sharing comprehensive, critical patient-centered data on patients with multiple chronic conditions across home, community, clinic, and research settings. This will facilitate coordinated, patient-centered care planning as well as pragmatic PCOR. Most Medicare fee-for-service beneficiaries living with dementia also have at least five other chronic conditions. Care coordination is essential for ensuring high quality care for these patients.
- Joan Weiss provided **HRSA** updates. HRSA funds the Geriatric Workforce Enhancement Program (GWEP). Grantees are required to offer dementia care training. During fiscal year (FY) 2020, grantees trained more than 63,000 participants through 455 educational offerings. HRSA also provided grantees with supplemental funding to train students and clinicians to offer telehealth services. During FY 2021, HRSA provided supplemental funding to 12 GWEP grantees to train the nursing home workforce to provide high-quality care while addressing the COVID-19 public health emergency, and to develop a national curriculum for this purpose. GWEP grantees train primary care sites and care systems to become age-friendly according to Institute for Healthcare Improvement standards. To date, GWEPs have trained 235 sites to receive Level 1 recognition and 85 sites to earn Level 2 recognition. Between April 1 and June 20, 2021, 744 people earned continuing education credit through HRSA's Alzheimer's Disease and Related Dementias curriculum. HRSA is collaborating with ASPE to develop a report to Congress on the capacity of the dementia specialists workforce.
- Bruce Finke provided **IHS** updates. In FY 2021, Congress appropriated \$5 million for IHS to address Alzheimer's disease. IHS is consulting with Tribal and urban Indian organizations to determine how to use the funding. Input has included recommendations to develop Tribal models of care; provide training in and build capacity for primary care; improve diagnosis and management; and improve outreach and services for family caregivers, with recognition of grandchildren who serve as caregivers. Funded activities will align with the National Plan to Address Alzheimer's Disease and the National Family Caregiving Strategy. IHS

is collaborating with the Northwest Portland Area Indian Health Board to launch an Extension for Community Healthcare Outcomes program to offer dementia care training to clinicians and caregiver support staff. IHS also is working with the American College of Emergency Physicians to support geriatric emergency department accreditation for IHS and Tribal emergency departments.

- Lisa McGuire provided **CDC** updates. CDC published findings of research on subjective cognitive decline among caregivers of people living with dementia. CDC's website updates include information about support for caregivers and ensuring older adults with dementia remain safe from extreme cold during winter months. CDC grantees have offered webinars on topics related to geriatric care and dementia caregiving, as well as dementia research and policy. CDC soon will release a funding announcement to existing prevention research centers for a thematic network for risk reduction. CDC will offer a risk reduction webinar in February or March 2022.
- Richard Hodes presented **NIH** updates. NIH currently funds 365 clinical trials related to dementia. Trials are testing pharmacological, non-pharmacological, and caregiving interventions. NIH has expanded its Alzheimer's disease and related dementias research centers network since the last federal update. NIH also has funded Artificial Intelligence and Technology Collaboratories for Aging Research to develop, validate, and disseminate innovative technology to monitor people living with dementia and enhance their connections with care providers. NIH offers pre and post-doctoral fellowships and early career development training to promote dementia research workforce diversity. The Alzheimer's Disease Sequencing Project currently focuses on phenotypic data harmonization, expanding study samples to increase diversity and representativeness, functional genomics, and machine learning and artificial intelligence. The National Institute on Aging is collaborating with the Veterans Administration to increase veterans' participation in dementia research. [Alzheimers.gov](https://www.alzheimers.gov) is now available in Spanish. NIH will convene an Alzheimer's Disease and Related Dementias Summit March 22-23, 2022.
- Erin Long presented **ACL** updates. ACL will fund 23-26 grants to states and communities to deliver and evaluate direct services through the Alzheimer's Disease Programs Initiative. The Alzheimer's and Dementia Resource Center will offer a series of ten webinars in 2022. Participants can earn continuing education credit. The National Alzheimer's and Dementia Resource Center (NADRC) and Minority Aging Technical Assistance and Resource Center are collaborating to improve development and dissemination of resources for the Hispanic/Latino community. NADRC also is working with a MHP Salud to identify potential participants in MHP Salud's learning collaborative. NADRC will offer virtual learning sessions on how organizations maintained and improved services to Hispanic/Latino adults living with dementia and their caregivers during the COVID-19 pandemic.

National Plan to Address Alzheimer's Disease: 2021 Update

Tisamarie Sherry, MD, PhD

Helen Lamont, PhD

- A risk reduction subcommittee was formed. The subcommittee recommended adding a goal of risk reduction to the National Plan and making the subcommittee permanent. HHS adopted the goal: Accelerate Action to Promote Healthy Aging and Reduce Risk Factors for Alzheimer's Disease and Related Dementias. HHS will make progress toward achieving this goal by implementing action steps specified in the National Plan; convening the subcommittee; coordinating with other health promotion and disease reduction efforts; focusing on community risk reduction; and coordinating with state, local, and community-based organizations.

Long-term Impact of Military-relevant Brain Injury Consortium-- Chronic Effects of Neurotrauma Consortium (LIMBIC-CENC)

David X. Cifu, MD, Senior Traumatic Brain Injury Specialist, U.S. Department of Veterans Affairs

- Since 2013, Dr. Cifu's team has been conducting a national prospective cohort study. Data are linked with several federal datasets, including health data on 2.2 million veterans with and without traumatic brain injury. The research team has developed knowledge translation products for patients, clinicians, researchers, and other stakeholders, including a dementia prognostic tool, regulatory tracking system, and publication database. To date, the team has recruited 2,000 of a targeted sample of 3,000 participants, with a retention rate greater than 85%. Currently, participants are representative of Iraq and Afghanistan conflict veterans. Results show that number of injuries, including injuries incurred outside of military service, is related to fluid biomarkers. Participants with at least three brain injuries and those with concomitant post-traumatic stress disorder are more likely than others to report mild symptoms of cognitive decline, but do not demonstrate decline on standardized tests. Traumatic brain injury is linked to cardiovascular disease, depression, post-traumatic stress disorder, suicide risk, and sleep disorders. Cardiovascular disease and traumatic brain injury are risk factors for dementia. Key findings will be published in February 2022 in a special edition of *Brain Injury* and through podcasts. The team aims to find interventions that will prevent dementia following traumatic brain injury and hopes current participants will consent to participate in intervention studies. The research team welcomes collaborators.

Capacity of Dementia Specialists: Report to Congress

Elizabeth Gould, MSW, LCSW, Senior Research Public Health Analyst,
RTI International

- The 2021 Consolidated Appropriations Act directs HRSA and ASPE to develop a report on national capacity of dementia specialists, including assessment of screening capacity, provider shortages, barriers to detection and care access, and recommendations to streamline diagnosis and address provider shortages. The report is based on an environmental scan and interviews with subject matter experts.
- Timely dementia screening and diagnosis requires a sizable and knowledgeable workforce.
- People with intellectual or developmental disabilities require different screening instruments than those used for the general population.
- Medicare covers dementia screening, assessment, and care planning services.
- Patient-associated barriers to screening and care include stigma, lack of knowledge, lack of support, affordability, and transportation.
- Provider-associated barriers include doubting utility of diagnosis, perceiving that treatment options are limited, and insufficient knowledge of resources.
- Health care system-level barriers include resource constraints, patient visits being too short, and lack of access to specialist services.
- The report shows a current and projected shortage of dementia care specialists across the United States. By 2025, analysts project a shortage of 26,980 geriatricians, 820 neurologists, and 52,000 primary care physicians, partly due to organizational and systemic barriers including inadequate financial incentives. Shortages disproportionately affect rural communities.
- Promising practices for addressing shortages include targeted education and training, interprofessional team-based care, and telehealth. Federal education and training programs, such as GWEP, and state policies and programs support increasing dementia care workforce capacity.

Discussion

- Panel members said that neuropsychologists and geriatric care planners are key contributors to workforce capacity.
- A panelist emphasized the importance of removing the barrier of stigma and of incentivizing people to pursue careers as dementia care specialists.

- A panelist asked whether the report discusses how recent changes in dementia diagnosis and care, such as innovations in diagnostic testing and drugs that target amyloids, affect capacity. Ms. Gould said interviewees discussed potential implications of these innovations. She invited further input on how the report can address this issue. Dr. Carlsson said this is a key topic for subcommittees to consider.

Panel Discussion: Barriers to and Recommendations for Addressing Dementia Assessment Challenges with Adults with Neuroatypical Conditions

“Introduction”

Matthew Janicki, PhD

- The Affordable Care Act calls for early assessment for cognitive impairment as part of annual wellness visits. It can be challenging for clinicians to discern newly emerging cognitive changes in people with pre-existing cognitive limitations. Current federal guidance does not include protocols for assessing these patients, which can lead to diagnostic errors, lack of treatment, or inappropriate treatment.
- The Lumind IDSC Foundation and the National Task Group on Intellectual Disabilities and Dementia Practices convened a Neuroatypical Conditions Expert Consultative Panel to examine barriers to screening, detection, and assessment of dementia in adults with neuroatypical conditions and to identify adaptations that could be employed when examining adults with these conditions. The panel identified barriers related to assessment, communication, and condition.
- Assessment barriers include instruments being normed on data from neurotypical adults and lack of information about whether and how to use instruments with neuroatypical adults.
- Communication barriers include impairments associated with neuroatypical conditions and clinicians’ difficulties understanding patients who have these impairments.
- Condition barriers include clinicians’ lack of awareness or understanding of neuroatypical conditions and confounding symptoms and conditions that present challenges to assessment.
- Another key barrier is lack of reimbursement for assessing adults at risk for younger onset dementia.

- The panel found that most standardized instruments are not appropriate for assessing patients with neuroatypical conditions and that most clinicians find assessing these patients for dementia to be challenging.
- The panel recommended: (1) broadening federal guidance to include adaptations of assessment practices to accommodate neuroatypical conditions; (2) enhancing education for practitioners to increase understanding of neuroatypical conditions and how to diagnose and plan for care for patients with these conditions; and (3) expanding research to contribute to the evidence base on assessing neuroatypical conditions as part of cognitive impairment screenings.

“Assessment Issues in Detecting Cognitive Impairment Among Persons with Intellectual Disabilities”

Lucille Esralew, PhD

- Dementia onset is earlier among people with Down syndrome (average age is early 50s) than among neurotypical adults. Deterioration is often rapid and is characterized more by executive function decline than memory loss. Therefore, it is important to establish baseline status of cognitive and behavioral functioning in these patients and to assess status at short intervals. Down syndrome often co-occurs with conditions that make it difficult to diagnose cognitive decline. These include sensory loss, thyroid disorder, sleep apnea, monoclonus seizures, communication issues, catatonia, and regression syndrome. Practitioners without training in care for patients with Down syndrome may misattribute behavioral and cognitive changes to Alzheimer’s disease. Biomarkers may support differential diagnosis.
- People with intellectual disabilities other than Down syndrome have a broad range of disabilities, some with unknown etiology. There is a need for longitudinal study of the trajectory of these conditions, including cognitive and behavioral functioning at baseline and in later life. As with Down syndrome, symptoms can confound dementia diagnosis. It would be useful to develop and incorporate a brief in-office screen into annual wellness visits that indicates whether patients need formal, comprehensive assessment. It also would be useful to train family or residential care staff, who are best positioned to observe behavioral and cognitive changes in those for whom they care, about signs of dementia and need for referral to a qualified clinician.
- Adults with intellectual disabilities disproportionately experience mental illness, though epidemiological data are limited, in part due to lack of validated standardized instruments to measure mental health issues in this population. Dr. Esralew advocated using *The Diagnostic Manual--Intellectual Disability, 2nd Edition*, which provides diagnostic guidelines.

“Assessment of New Onset Decline in Persons with Severe Mental Illness”

Philip Harvey, PhD, Professor of Psychiatry, University of Miami Miller School of Medicine

- Symptoms that define schizophrenia and those that define major neurocognitive disorders overlap. People with schizophrenia experience cognitive impairment, with levels of impairment remaining stable over the life course.
- At age 66, 27.9% of people with schizophrenia are diagnosed with dementia, compared with 1.3% of people without a schizophrenia diagnosis. The percentages at age 80 are 70.2 and 11.3, respectively. The high rates of dementia diagnosis among people with schizophrenia may be due to the prevalence and severity of cognitive impairment associated with schizophrenia. Research indicates that most people with schizophrenia whose responses to cognitive assessments meet the criteria for a dementia diagnosis do not meet neuropathological criteria for a diagnosis of Alzheimer’s disease or other dementia.
- A matched comparison group study found that people with schizophrenia and people with Alzheimer’s disease had equivalent learning rates. People with schizophrenia demonstrated better recall and recognition than those with Alzheimer’s disease and performed less well on tests of verbal skills and executive function. Estimates of high prevalence of schizophrenia among people with dementia may be due to lack of cognitive assessment until later in life.
- Longitudinal assessment is necessary for accurate measurement of dementia among people with schizophrenia. Assessment should focus on delayed recall and recognition and should include input from informants who know the patient well.
- People with schizophrenia become increasingly sensitive to anticholinergic burden with age. Assessment should consider this as a potential cause of cognitive deficits.

Panel Discussion: Integrating Caregivers and Addressing Health Care Disparities in Clinical Care

“Introduction”

Venoreen Browne-Boatswain

Helen Bundy Medsger

- Caregivers with lower incomes may not have access to technology that aims to improve dementia care. Older caregivers may not be able to use this technology, or may not be interested in it.
- Caregivers may hesitate to seek help to address their own mental health needs. Dementia care approaches should consider how to address this challenge.
- Clinicians and researchers now recognize that informal caregivers are essential to dementia care.

“Improving Lives of Rural Residents Who Face Dementia Disparities”

Lisa Wiese, PhD, MSN, RN, GERO-BC, PHNA-BC, Florida Atlantic University Christine E. Lynn College of Nursing

- Dr. Wiese works in a rural area of Florida where more than 80% of residents are ethnic minorities, the poverty rate is 41%, and agricultural work is the primary means of employment. The typical health literacy level is lower than 3rd grade. Nearly half of residents do not have a computer and nearly half do not know how to use computers. The area is affected by more than a dozen risk factors, resulting in risk for Alzheimer’s disease and related dementias being 2-4 times higher than risk for Florida coast residents.
- Informal caregivers in the community have reported that what they most need is assistance with communicating with and managing behaviors of the people with dementia for whom they care.
- Dr. Wiese conducted community-based participatory research to identify and address needs for education about Alzheimer’s disease. Her team trained community members to be health educators. Churches were key partners in this effort.
- Slightly more than 80% of participants in a community survey indicated interest in cognitive assessment. Participants did not perceive that their care providers were able to conduct these assessments.
- Due to low levels of literacy, assessments that rely on reading and writing skills are not appropriate for this population.

- The team is conducting the Optimizing Rural Community Health through Interdisciplinary Dementia Detection and Care project, for which nursing students work with community-based health educators to conduct education and screening and facilitate visits to clinicians, who are trained to provide dementia detection and care. Students and community-based health educators also connect patients with community resources.
- Results indicate that the following are effective strategies for reducing disparities in dementia care: working with faith-based organizations to train health educators, home visits from clinicians, ability to bill for home visits, training and providing a support network for informal caregivers, and offering resources to address community needs.

“Enhancing Support for Caregivers of Veterans”

Leah Christensen, LCSW, Clinical Program Coordinator, Caregiver Support Program, Veterans Health Administration

- The Veterans Health Administration launched its Caregiver Support Program in 2011. Research has shown that well-supported caregivers are critical for veterans to thrive.
- The program includes the Program for Comprehensive Assistance for Family Caregivers, which supports informal caregivers of veterans with service-connected disabilities. Services include education and training, respite care, counseling, access to health care, and financial support and planning services. The aim is to allow veterans to remain at home for as long as possible.
- The Program of General Caregiver Support Services provides support including coaching, skills training, and resources to informal caregivers of all veterans, regardless of whether the veteran has a service-related disability.
- Program activities include personalized one-on-one psychosocial support and holistic health and well-being coaching as well as support groups.
- Caregiver training addresses suicide prevention.
- The program offers education and support specifically for dementia care. Materials include fact sheets and online videos.
- Resources include a support line and peer support mentoring.
- The program offers an annual caregiver summit and an annual resource fair.
- The Veterans Health Administration aims to change its culture of health care to be more inclusive of caregivers, most of whom report that veterans’ health care teams do not engage them as part of the team. The Campaign for Inclusive Care

encourages providers to **Consider** who else should be on the care team, **Acknowledge** caregivers' efforts, **Review the caregiver's role** to determine which tasks they are comfortable with, and **Encourage** caregivers to seek and accept support. The Veterans Health Administration offers Academy for Inclusive Care online training in these principles.

Public Comments

Dr. Lamont reminded commenters that input regarding CMS's policies on reimbursement for aducanumab treatment should be addressed to CMS, not the Advisory Council, and said the meeting summary would not be shared with CMS.

- Laurie Waters was diagnosed with Alzheimer's disease at age 52. Available medications have not helped her. She has been excluded from clinical trials for being too young and has been unable to participate in other trials due to travel and financial burden. She asked the council to urge CMS to consider all Alzheimer's disease patients when making policies about treatment coverage.
- Ed Patterson said the CMS decision to reimburse for aducanumab only for clinical trial participants is unfair and will exacerbate disparities. He has been diagnosed with Alzheimer's disease and is not able to participate in trials. He believes the decision denies him the opportunity for a longer productive life.
- Dale Rivard has mild cognitive impairment. He has tried to participate in clinical trials but has been unable to due to distance between his home and the nearest study site. If he were able to participate in a trial, he could be placed in a no-treatment group, allowing the disease to progress.
- Jim Butler was diagnosed with Alzheimer's disease approximately 6.5 years ago. He has participated in clinical trials for most of the time since. Mr. Butler said it is absurd to restrict coverage for costs of a drug to treat a currently incurable disease. Not everyone is able to participate in a clinical trial. He advocated making medications to treat Alzheimer's disease affordable. Aducanumab currently costs \$58,000 annually, which is prohibitively expensive for almost everyone.
- Ian Kremer of the Leaders Engaged on Alzheimer's Disease Coalition thanked the council for its work to add the 6th goal to the National Plan to Address Alzheimer's Disease. He said that it is critical for the public to submit comments to CMS regarding aducanumab coverage. The current decision is a draft; 20 days are available for comments. Mr. Kremer said CMS has not explained why FDA trial results are not sufficient to allow coverage, which has been the case for drugs to treat cancer and rare diseases. He said CMS should work with FDA to ensure equity issues are addressed in confirmatory trials. CMS's draft decision applies to an entire class of therapies, some of which are still in clinical trials,

which may unnecessarily delay approval of safe drugs for years and deny treatment to people living with Alzheimer's disease, who have no alternatives.

- Mike Zuendel took care of both of his parents when they had Alzheimer's disease. He has been diagnosed with Alzheimer's disease. He has been taking aducanumab with no ill effects for several months and is concerned that he will have to stop due to the CMS decision. Aducanumab aims to arrest mild cognitive decline. If decline becomes more severe, the drug cannot help and there are no alternatives. Mr. Zuendel said coverage for aducanumab should not be restricted unless a better alternative becomes available.
- Bart Devon, Senior Director of Public Policy, National Down Syndrome Society, said the amyloid precursor protein that is the basis for Alzheimer's disease is present on chromosome 21, which people with Down syndrome have three copies of, thus increasing their risk for Alzheimer's disease. Approximately 90% of people with Down syndrome experience Alzheimer's disease, with earlier symptom onset and faster progression than is typical for the general population. Alzheimer's disease is the most prevalent cause of death among people with Down syndrome. The National Down Syndrome Society reiterated the recommendation it made in October 2021 for the Council to form a committee to focus on how HHS can improve diagnostic and clinical supports for people with intellectual and developmental disabilities. Mr. Devon said the CMS restrictions on aducanumab coverage include a protocol that excludes people with intellectual disabilities. If the restrictions and protocol are implemented, evidence on drug effectiveness will not be applicable to people with intellectual disabilities. He said the Down syndrome community needs champions in the Federal Government.
- Laura Cohen of Eli Lilly and Company said CMS restrictions on aducanumab coverage undermine goals of the National Alzheimer's Project Act and the National Plan to Address Alzheimer's disease by applying the same coverage standard to an entire class of drugs and not offering a plan for moving beyond CED. The National Plan includes acceleration of treatment development and deployment by the year 2025. FDA approval followed by CMS restrictions indicates a lack of HHS coordination, while the Plan directs HHS to deploy a coordinated effort. The company encouraged council members to submit public comments to CMS.
- Allison Lindauer, a clinical researcher at the Oregon Aging and Disability Resource Center, studies telehealth utilization for clinical assessment and caregiver support. Results show that telehealth is an effective approach for reaching rural patients and care providers. Many rural communities lack broadband access. Dr. Lindauer asked the Council to recognize broadband access as a high priority need.

- Michael Ellenbogen of USAgainstAlzheimer’s is living with Alzheimer’s disease. He said he wants to avoid suffering the latest stages of the disease and to die with dignity. He advocated for a legal right to die in the United States and pointed out that some other countries have policies recognizing this right.
- Stanley Terman, a psychiatrist and bioethicist, has created a patient decision aid that communicates wishes for clinicians to cease assisted feeding and hydrating. This decision is legal and does not require policy change, but is controversial. Not all clinicians honor advance directives. Dr. Terman has published information about strategies for ensuring patients’ directions are followed.
- Matthew Sharp, Advocacy Manager for the Association for Frontotemporal Degeneration (AFTD), said the term “Alzheimer’s disease and other related dementias” is confusing. He noted that the public is unaware of much critical information about dementia; confusing nomenclature contributes to this problem. The Dementia Nomenclature Initiative seeks to address this issue. AFTD encourages the Council to continue to support the initiative and to adopt its nomenclature and communication framework.

Concluding Remarks

Dr. Carlsson noted that the Council’s next meeting will focus on risk reduction and will be held on May 2 and 3, 2022. Another meeting is planned for July 25, 2022.

The meeting adjourned at 5:00 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>.