

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

Washington, DC and Virtual Meeting

July 31, 2023

Advisory Council Members in Attendance

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

General Proceedings

Chair Cynthia Carlsson called the meeting to order at 9:32 a.m. Eastern Daylight Time.

Welcome, Logistics, Introductions, and Announcements

Dr. Carlsson meeting participants and reviewed the meeting agenda. She invited meeting participants to introduce themselves.

Updates from Alzheimer’s Association International Conference

Cindy Carlsson, MD, MS; Joanne Pike, DrPH; Randy Bateman, MD

More than 11,000 people from more than 100 countries attended the hybrid conference, which offered more than 600 podium presentations and 4,500 posters. The hybrid platform supported increased participation and will be maintained for future conferences. More than one-third of participants were younger than 35, which was an increase in participation of early career investigators compared with previous years. Presentations covered a broad range of topics, including the NIA and Alzheimer’s Association (NIA-AA) Symposium on Enabling Precision Medicine for Alzheimer’s Disease, plenary sessions on diverse topics including tau positron emission tomography (PET) and the epidemiology of dementia in Africa (the first plenary session that has focused on dementia in Africa), and a special plenary session on the downstream effect of biomarkers on anti-amyloid therapies. Participants presented and sought input for the draft proposal for new Alzheimer’s disease (AD) diagnostics criteria. The NIA-AA Research Framework is on the Alzheimer’s Association website and is open for public comment for 30 days following the conference presentation.

Researchers presented findings on the clinical and cognitive effects of drugs that remove amyloid plaques. People with lower tau pathology at treatment initiation benefit more than people with higher pathology at treatment initiation. Researchers also are developing approaches to tracking disease progression through blood biomarkers, which are now 95%-97% accurate.

CMS Guiding an Improved Dementia Experience (GUIDE) Model

Chiquita Brooks-LaSure, CMS

GUIDE aims to improve care coordination through service integration. The model’s goals are to improve quality of life for people with dementia, reduce strain on unpaid caregivers, help people remain in their homes and communities, and prevent or delay long-term nursing home placement. GUIDE supports President Biden’s Executive Order to increase access to high-quality care and to support caregivers. GUIDE also supports the goals of the National Plan to Address Alzheimer’s Disease. GUIDE will include a sustainable alternative payment model for standardized dementia care, including assessments, care coordination, ongoing monitoring, medication management, and a 24/7 support line. GUIDE services include navigators who provide individualized, comprehensive evaluation and care plans for people with dementia and their families to ensure that they have access to the services they need. The model will provide linkage between community-based service providers, who may offer such services as training on dementia caregiving best practices, and the clinical care system. GUIDE will support respite care at adult day care centers and nursing facilities for overnight stays. The model will advance health equity by offering resources that expand underserved communities’ access to care.

The co-sponsors of the Comprehensive Care for Alzheimer's Act, Senators Debbie Stabenow and Shelley Capito, endorsed GUIDE and said it is consistent with their bill. Senator Ed Markey also endorsed GUIDE, saying it will help people with dementia and their families get the comprehensive care they need. Dr. Carlsson said the model addresses some of the Council's longstanding priorities, such as coordinated care, need for caregiver support, need for help navigating the health care system, and need for comprehensive care models. She applauded the GUIDE model for prioritizing underserved populations and communities.

Ms. Medsger, who has 35 years of experience as a family and community caregiver, said the GUIDE model is the culmination of years of advocacy. Lack of support services has affected the physical, emotional, and financial well-being of herself, her loved ones, and the caregivers she works with as an advocate. Ms. Medsger said GUIDE acknowledges and responds to the needs of people with dementia and their caregivers through strategies such as reducing costs of care.

Discussion

Representatives of the CMS Innovation Center addressed questions about GUIDE.

- CMS Innovation Center will administer GUIDE, which will be implemented by eligible providers who apply to participate. CMS expects to request applications in fall 2023. CMS hopes for broad participation.
- The model will be tested rigorously, probably by comparing results to those of reference populations. CMS Innovation Center intends to implement GUIDE nationally if it achieves target outcomes, which are improved beneficiary quality of life, reduced caregiver strain, and reduced rates of long-term nursing home placement. While reducing strain is expected to improve caregivers' health, CMS does not currently plan to evaluate GUIDE's impact on caregiver health outcomes.
- GUIDE will address critical needs for support and social services of people with dementia and their caregivers.
- GUIDE will support technical assistance, payment, and infrastructure development for safety net providers, and existing and new organizations serving underserved populations.
- GUIDE will expand data collection activities necessary for identifying disparities.
- Participating organizations will be required to submit annual health equity plans and track implementation progress.
- The model includes detailed requirements for care delivery, including 24/7 access to a member of the health care team.
- Allowing telehealth service delivery is expected to encourage rural and remote providers to participate in GUIDE.
- GUIDE providers will be reimbursed using a dementia care management payment model that requires provision of specified services such as caregiver

support and education, navigation services, linkages to community-based services, and respite care, including respite for care providers.

Federal Updates

- **Erin Long, ACL.** ACL has awarded 12 grants through the Alzheimer's Disease Programs Initiative for States and Community programs. Applications for new awards are due August 7, 2023. Grantees offer services in 29 states and Puerto Rico. Dr. Long said ACL planned to award grants for the Alzheimer's Call Center, Lifespan Respite Program, and Community Care Corps in August and September 2023. The National Alzheimer's and Dementia Resource Center has offered several webinars and will offer a webinar on Memory Care, a program that offers support, education, and creative activities for people with dementia and their caregivers on August 29, 2023. ACL developed an advanced planning guide and a document summarizing highlights of grantee-developed resources and will soon publish a guide for supporting people with dementia in making social connections. The National Institute on Disability, Independent Living, and Rehabilitation Research Enhancing Neurocognitive Health, Abilities, Networks, and Community Engagement Center has disseminated research findings through webinars and conferences.
- **Arlene Bierman, AHRQ.** AHRQ recently published a report on developing a person-centered care system for older adults, caregivers, and communities.
- **Lisa McGuire, CDC.** CDC redesigned its website. CDC expects to fund 35 Building Our Largest Dementia (BOLD) infrastructure grants in the near future. The Healthy Brain Resource Center currently offers more than 300 credible and practical resources, including a searchable database of states' and territories' AD and related dementias (AD/ADRD) plans. Dr. McGuire and colleagues recently published an article on promoting healthy aging to reduce dementia risk in *Public Policy & Aging Report*. CDC hosted the inaugural Dementia Risk Reduction Summit in Atlanta, GA, May 16-17, 2023.
- **Sarah Fontaine, DOD.** DOD funds research on AD/ADRD through the Congressionally Directed Medical Research Program (CDMRP) Peer Reviewed Alzheimer's Research Program (PRARP). Congress determines CDMRP research topics and budget. People affected by the medical issue being studied by CDMRP are involved in proposal review, including funding recommendations. Depending on race and ethnicity, military service members are between 2 and 8 times more likely than non-service members to develop dementia. PRARP supports research on the association between traumatic brain injury and other military service-related risk factors and AD/ADRD. It also supports research on how to reduce burden associated with AD/ADRD and improve quality of life for the people affected. Across federal agencies, PRARP leads investment in research on diagnosis, assessment, and monitoring; population studies; and

dementia care and impact on disease. Current focus areas include diversity, equity, and inclusion and risk reduction. Researchers are required to collaborate with communities.

- **Julie Crowder, Valerie Jones, Bruce Finke, IHS.** The IHS Alzheimer's Grant Program funds grants and program awards for developing models of care for addressing AD in Indian Country; outreach and awareness efforts; workforce development, including education and training; caregiver support coaching; and program support and data management. Workforce development efforts focus on Tribal capacity building and developing clinical champions through the Indian Health Geriatrics Pilot, Early Dementia Detection Initiative in Dental Clinics, the Geriatric Emergency Department Accreditation Initiative, the Nurse Fellowship Pilot, Indian Country Dementia Clinical Extension for Community Healthcare Outcomes (ECHO), Indian Country Dementia Caregiver Support ECHO, and other training efforts such as a 28-module dementia care specialist course. Outreach and awareness efforts have included a models of care webinar series and participation in an ACL Title VI program national technical assistance training.
- **Teresa Buracchio, Food and Drug Administration (FDA).** Lecanemab was converted from an accelerated to a traditional approval on July 6, 2023, based on results of a Phase 3 randomized controlled clinical trial (Clarity AD). Researchers found statistically significant treatment effects on clinical symptoms, brain amyloid plaque levels, and cognitive functioning. The medication carries a boxed warning for risk of amyloid-related imaging abnormalities (ARIA). FDA recommends apolipoprotein E4 genotype testing to assess risk. The medication is contraindicated for patients with serious hypersensitivity to Lecanemab.
- **Shari Ling, Joe Hutter, David Dolan, CMS.** The CMS national coverage determination specifies that FDA traditional approval for any monoclonal antibody targeting amyloid will lead to CMS coverage for that drug. CMS has launched a national registry page for Lecanemab. In addition, CMS proposes to end coverage with evidence development for PET beta amyloid imaging and to permit Medicare Administrative Contractors to make coverage determinations. The comment period for this proposal will remain open until August 16, 2023. CMS is proposing to pay for new caregiver training services provided by a qualified professional, and for principal illness navigation services to help people with serious, high-risk conditions connect with appropriate clinical and support services. The comment period for these proposals is until September 11, 2023.

Charting the Course to Better Brain Health: Healthy Brain Initiative State and Local Road Map for Public Health, 2023-2027

Lisa McGuire, PhD; Joanne Pike, DrPH

The fourth version of the Healthy Brain Initiative, “Charting the Course to Better Brain Health,” was released in late June 2023 and has been downloaded more than 1,500 times. More than 800 people attended the webinar launch. The initiative motto is “Everyone deserves a life with the healthiest brain possible.” Prevalence and costs of AD are expected to increase dramatically between now and 2050. Public health action affects brain health across the life course through risk reduction efforts, early detection and diagnosis, and support of safe, high-quality care for people with dementia and their caregivers. The Road Map describes a public health strategy based on recent scientific evidence. New points in the current version include acknowledging that community partnerships are essential and foundational, health equity should be fully integrated into all actions, and newly created standardized outcome measures. The action framework identifies health equity as the core principle. Action domains are: (1) strengthen partnerships and policies; (2) measure, evaluate, and utilize data; (3) build a diverse and skilled workforce; and (4) engage and educate the public. Actions aim to reduce risk, support early detection and diagnosis, and support linkages between community and clinical care. Targeted partnership and policy outcomes are increased community partnerships, increased integration with other chronic disease efforts, and increased policy action and implementation. Targeted measurement and evaluation outcomes are increased data availability, quality, and utilization and increased data-informed decision making and action. Targeted outcomes in the domain of building a diverse and skilled workforce are reducing stigma and bias about cognitive decline and increasing the knowledge and skills of the current and future workforce. Targeted outcomes of the public engagement and education domain are to increase knowledge about brain health, dementia risk factors, and benefits of early detection and diagnosis and to increase public awareness and use of services for people living with dementia (PLWD) and their caregivers. The document presents case studies of state and local health departments. An implementation guide, topic-specific resources, and evaluation tool are in development.

Discussion

- BOLD grantees can braid funding with complementary initiatives.
- CDC’s One Million Hearts prioritizes the same people at the same points of care using the same types of interventions. BOLD collaboration with One Million Hearts could increase the reach and impact of both initiatives. Initiative teams are working to coordinate efforts.
- Healthy Brain Initiative dissemination is primarily through public health agencies.

FY 2025 Professional Judgment Budget

Richard Hodes, MD

Congress requires the NIH Director to submit to the President an annual budget for initiatives that support the National Alzheimer's Plan Act (NAPA). Academic, industry, government, and advocacy stakeholders provide input. NIH staff develop comprehensive milestones that align with research priorities, then estimate the funds necessary for achieving them. NIH uses the eight categories of the Common Alzheimer's Disease Research Ontology (CADRO) as a framework for developing the budget and narrative. Using CADRO, NIH identified six research areas requiring additional resources: epidemiology/population studies; disease mechanisms; diagnosis, assessment, and disease monitoring; translational research and clinical interventions; dementia care and impact of disease; and research resources. International studies are an additional cross-cutting domain requiring additional resources. A total of approximately \$4.1 billion is needed for FY 2025, which is approximately \$3.2 million more than the baseline estimate.

The Alzheimer's and Related Dementias Progress Report summarizes the advances in dementia research NIH has funded over the past 10 years. Key accomplishments include advancing understanding of risk factors, genetics, and mechanisms of dementia; developing new drugs and other therapies; accelerating drug repurposing and combination therapy development; developing screening, diagnostic, and monitoring tools; advancing research on lifestyle interventions; increasing understanding of how social and environmental factors affect dementia risk and disparities; and expanding research on dementia care and supports for care partners. NIH now offers a searchable database that tracks funding initiatives and activities in the United States and another that tracks international efforts. NIH anticipates launching the Exceptional, Unconventional Research Enabling Knowledge Acceleration Innovation Challenge in September 2023 to support competition for discovering the best data, methods, and strategies for early prediction of AD/ADRD.

The National Institute of Neurological Disorders and Stroke (NINDS) led 14 funding announcements in FY 2023 and plans to lead the same number in FY 2024. Funding priorities include workforce training, as well as research on social determinants, modifiable risks, disease mechanisms and pathology, microbiome, COVID-19 and dementia, clinical trials, biomarkers and diagnosis, and translational research. On September 28-29, NINDS will offer a workshop on anti-amyloid beta passive immunotherapy for AD and ARIA.

Presentation of Subcommittee Recommendations

“Research Subcommittee Recommendations”

Randy Bateman

The Research Subcommittee submitted the following recommendations:

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 (DMTs).
3. Implement research of active dementia care models to compare effectiveness.
4. To address health equity and representation in research, representation and diversity in AD/ADRD clinical trials should be increased.
5. Improve translation from scientific discovery to health impact.
6. Implement scientific and evidence-based evaluations of factors for decision making.

“Risk Reductions Subcommittee Recommendations”

Joanne Pike

The Risk Reductions Subcommittee submitted the following recommendations:

1. Identify priorities for and track progress toward addressing cognitive decline and dementia risk factors across the lifespan.
2. Accelerate public health and aging network action on addressing the risk factors with the strongest evidence of beneficial impact on dementia prevalence, particularly for communities or target groups at greatest risk.
3. Identify and accelerate efforts to reduce risk and intervene early in clinical care.
4. Initiate and fund research to strengthen the strategies for addressing the potential risk factors for dementia. Appropriate non-federal governmental entities and private sector organizations should work to improve brain health.
5. Establish a set of dementia risk reduction policies at the federal, state, and local level that will address risk factors, including the social determinants of health, for cognitive decline and dementia.

“Clinical Care Subcommittee Recommendations”

Maria Ortega

The Clinical Care Subcommittee submitted the following recommendations:

1. Increase resources to educate the public (including patients, families/caregivers, health care administrators, clinicians, and community members) and increase awareness about the importance of AD/ADRD clinical care, including risk reduction, early detection, accurate diagnosis, person-centered care models, DMTs, clinical research participation, and available resources for PLWD and their families and caregivers.

2. Accelerate efforts in clinical care to promote healthy cognitive aging, dementia risk reduction, early detection, accurate diagnosis, and early intervention and management of AD/ADRD, including co-morbid health conditions of PLWD.
3. Implement solutions to address the geriatric and gerontology workforce crisis through training, continuing education, mandated standards, and improved pay to better address the needs of persons living with AD/ADRD and their families and caregivers.
4. Encourage people living with AD/ADRD and their designated care partners to be integral parts of the clinical care team and foster coordination of comprehensive, person-centered dementia care with home and community-based services.
5. Promote the implementation of evidence-based, non-pharmacological interventions to address behavioral and psychological symptoms of dementia.
6. Initiate a comprehensive dialogue involving a broad cross-section of experts to discuss implementation processes related to DMTs in the context of high-quality, person-centered care.
7. Promote the further development, evaluation, and practical implementation of effective person-centered health care models for AD/ADRD that integrate performance measures and payment models.
8. Promote health equity and eliminate barriers to the receipt and payment of clinical care services and long-term services and supports (LTSS) for adults living with dementia who are under age 65.

“Long-Term Services and Supports Subcommittee Recommendations”

Carrie Molke

The LTSS Subcommittee submitted the following recommendations:

1. Improve access to LTSS for people with dementia and their caregivers
2. Implement strategies that create the conditions for high-quality, person-centered and strengths based LTSS throughout the course of the disease.
3. Implement solutions to address the LTSS workforce crisis
4. Ensure that family and unpaid caregivers of people with dementia have the support they need.
5. Implement new payment models to make LTSS more affordable and eliminate gaps in coverage among government programs that support people with dementia.
6. Implement strategies that support coordination, integration, and dementia capability.

Voting and Adoption of Recommendations

Voting members unanimously approved all recommendations.

Remarks from Departing Members

- **Dr. Carlsson** expressed appreciation for all she had learned from other Council members. She observed that COVID-19 had increased awareness of the vulnerability of people with AD, including their needs for social connection and support. Technology has supported social and professional connections as well as the expansion of telehealth. The workforce shortage has inspired innovative approaches to staffing. Dr. Carlsson observed that awareness of health inequity has increased and research has advanced. The FDA has approved the first treatment for an underlying cause of AD and also has approved new diagnostic tools.
- **Ms. Browne-Boatswain** said she appreciated the opportunity to learn about current research, dementia, and health disparities. She said she felt she had contributed little to the Council. She received no orientation and was unsure of what was expected of her. The Council uses technical terminology, which she is not familiar with. She often withheld her questions and opinions to avoid being perceived as a negative person. While no one prevented her from speaking, she suggested that the Council should more proactively include caregivers in discussions. She appreciates that focus on diversity, equity, and inclusion has increased during her tenure on the Council. However, more needs to be done to achieve a deep understanding of these issues and to make the changes necessary to address them.
- **Dr. Ortega** said she has applied what she has learned from her experience on the Council by advocating for more access to care in her community and by teaching health professions students about person-centered care.
- **Dr. Molke** expressed appreciation for Council members' commitment to improving lives of the people they serve. She agreed with Ms. Browne-Boatswain that Council members should feel prepared and welcomed to contribute. She agreed that orientation regarding the Council's purpose and how members can contribute would be helpful. She said that she appreciates that under Dr. Carlsson's leadership an orientation was offered to new Council members.
- **Dr. Janicki** said being on the Council has been a career highlight. He said he appreciated that the Council now places high priority on the needs of people with disabilities and has mentioned them throughout current recommendations. He emphasized the importance of in-person communication with other Council members.
- **Mr. Montminy** expressed appreciation for Council members' expertise, efforts, and willingness to share their personal experiences, and for the value of government programs that address dementia. He thinks the Council is uniquely positioned to lead the Nation in responding to scientific breakthroughs related to dementia.

Discussion: Approaches to Orienting New Members

- Dr. Carlsson requested input on how to orient new Council members. Without orientation, new members are initially unsure of the Council's purpose and their responsibilities. Council members said it would be helpful to receive training on the Council's role and responsibilities, as well as government agency functions and processes. Assigning senior members to serve as mentors would be helpful. The amount of work assigned to subcommittee chairs is challenging to complete in the time allotted. Council members pay for travel costs in advance, which is a barrier to lower income people joining the Council. ASPE should consider potential ways to overcome this barrier, since it is critically important to receive input from this group.

Public Comments

- ***Katie Brandt***, Director of Caregiver Support Services and Public Relations for the Massachusetts General Hospital Frontotemporal Disorders Unit, asked for continued and expanded NIH funding for research on frontotemporal dementia (FTD) and other young-onset, rare, atypical dementias, and for more training of health care professionals on how to diagnose FTD. Early diagnosis is critical for allowing patients and their families an opportunity to connect with communities of support, participate in research, and develop health care plans.
- ***Jim Butler***, an advocate with Voices of Alzheimer's, was diagnosed with AD 9.5 years ago. He pointed out that newly available treatments for AD are not a cure and are not accessible to everyone. Currently available medications are only helpful in the early stages of disease. He encouraged continued funding for research on potential treatments and efforts to overcome barriers to research participation, care, and treatment.
- ***Jill Scigliano***, Executive Director of Memory Care Home Solutions, has applied evidence-based interventions with the support of ACL grant funds. She said the GUIDE model will fill an enormous void in health care. She noted that caregivers are often ignored and sometimes blamed and criticized. Therapists should be reimbursed for educating caregivers about managing patients' behavioral and psychological symptoms. Occupational therapists should be included in comprehensive dementia care teams. Community-based organizations understand their communities and their resources. Many are delivering evidence-based services and are poised to implement the GUIDE model.
- ***Hampus Hillerstrom***, Chief Executive Officer at LuMind IDSC Foundation, has a 9-year-old son with Down syndrome. LuMind supports research related to Down syndrome and works to empower families. He pointed out that adults with Down syndrome are genetically predisposed to early onset AD, with a lifetime risk of 90%. AD is the leading cause of death among people with Down syndrome,

accounting for 75% of deaths. He works with other organizations and individuals to develop equivalency criteria for access to treatment with anti-amyloid drugs for people with Down syndrome. The group has identified four key adaptations needed for adults with Down syndrome: (1) minimum age requirements, since many people with Down syndrome get dementia in their early 40s, with an average age of 54 at the time of symptom onset; (2) assessment scales, since typical cognitive, behavioral, and functional assessments are not sensitive enough to detect cognitive decline in people with Down syndrome; clinicians should use tools validated with this population; (3) contraindications, since seizures, some immunological diseases, and hypothyroidism are common in adults with Down syndrome; and (*4) safety trials, since no trial of a medication targeting AD has yet included people with Down syndrome.

- **Kayla McKeon** said that people with Down syndrome disproportionately experience early onset AD, which can lead to decline of independent living skills and reliance on caregivers. Since no people with Down syndrome were included in trials of newly available drugs to treat AD, physicians may not be comfortable prescribing these potentially life-saving drugs to people with Down syndrome. Ms. McKeon said it is critical to include people with Down syndrome in clinical trials of treatments for AD so that this high-risk population has access to these treatments.
- **Terry Walter** said she lost her husband to FTD and amyotrophic lateral sclerosis (ALS). Her 8 children and 15 grandchildren are at risk for developing both diseases. Her husband participated in research that discovered the gene underlying ALS. Ms. Walter said FTD, ALS, and other degenerative brain diseases should be included in the Healthy Brain Initiative.
- **Katie Zanger**, volunteer ambassador for the Association for Frontotemporal Degeneration in South Carolina, shared that her father died of behavioral variant FTD complications in 2021. She is also a health professional. Ms. Zanger was part of the team that developed South Carolina's 5-year BOLD plan. She commended CDC's work on the most recent Healthy Brain Initiative Road Map. She agreed with making community partnerships the first priority since this is critical for leveraging limited public health resources. She endorsed using the term "dementia" rather than "Alzheimer's disease and related dementias." The latter term can support the assumption that dementia and AD are the same thing, which can make it more challenging for people who have less prevalent and less understood forms of dementia to get the care they need. Using accurate terminology is important for epidemiological research, ICD-10 codes, and insurance codes. Ms. Zanger stated that there is a need for more national registries for less common types of dementia.

Concluding Remarks

Dr. Carlsson noted that the Council's next meeting will be held in October 2023.

The meeting adjourned at 4:39 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>.