

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

Virtual Meeting

October 30, 2023

Advisory Council Members in Attendance

- *Non-Federal Members Present:* Adrienne Mims (Chair), Deke Cateau, Fawn Cothran, Roberta Cruz, Susan DeMarois, Keun Kim, Helen Bundy Medsger, John-Richard Pagan, Joanne Pike, Yakeel Quiroz, Rhonda Williams
- *Federal Members Present:* Arlene Bierman (Agency for Healthcare Research and Quality, AHRQ), Rebecca Ferrell (National Science Foundation, NSF), Bruce Finke (Indian Health Services, IHS), Sarah Fontaine (U.S. 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, HRSA)
- *Quorum present?* Yes
- *Advisory Council Designated Federal Officer:* Helen Lamont (U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, HHS/ASPE)

General Proceedings

Chair Adrienne Mims called the meeting to order at 12:04 p.m. Eastern Daylight Time.

Welcome and Introductions

Dr. Mims welcomed meeting participants, welcomed new Advisory Council members, discussed the purpose of the Advisory Council, and reviewed the meeting agenda. Council members introduced themselves.

Exploring Interventions to Reduce Dementia Risk

Joanne Pike, DrPH, Chair of the Subcommittee on Risk Reduction, introduced five presentations by experts from the field of dementia risk reduction.

SPRINT-MIND Intervention for Hypertension

Jeff D. Williamson, MD, Wake Forest University School of Medicine

Systolic Blood Pressure Intervention Trial -- Memory and Cognition in Decreased Hypertension (SPRINT-MIND) is a randomized controlled trial (RCT) study of over 9,000 volunteers that examines the relationship between reducing blood pressure and the risk for cognitive decline over a period of 5 years. Hypertension, or increased blood pressure, is incredibly prevalent and the percentage of people affected increases with age. About one-half of the United States population has high blood pressure by their mid-50s. Hypertension correlates strongly with increased dementia risk, but it was not known whether decreasing blood pressure would also lower rates of cognitive decline. The SPRINT-MIND study examined the impact of a more aggressive treatment of blood pressure on cognition over time. On average, participants took one additional blood pressure medication, and cognition was measured at various points in time using multiple scales. The final results of this study will be available in January 2024 and shared later in 2024. The initial analysis indicates that a more intensive treatment of blood pressure results in less cognitive decline. Treating blood pressure is beneficial at any age, but starting treatment earlier in life effects greater benefit. Any decrease in blood pressure seems to be beneficial, though outcomes are better if the goal is systolic blood pressure of 120 instead of 140. The study population was diverse, including a large percentage of participants who are African American and Hispanic.

Discussion

- Dr. Williamson shared that effect sizes were the same across all racial and ethnic groups.
- The costs for the additional (generic) drugs were about \$10-\$25 per month per person.
- In terms of compliance with taking medication, many of these medications can be combined into one tablet. There are plans to perhaps combine three medications in one tablet.
- There was a question about the correlation between cholesterol and dementia. Dr. Williamson indicated that there is a relationship between cholesterol and hypertension, and the Alzheimer's Association and the NIA have funded a large current study examining the use of cholesterol-lowering drugs in people over age 75 who have not had a prior stroke or heart attack. It is unknown whether medications for this group are generally harmful or helpful. Many of the people in this group also have hypertension. Results will be available in about 6 years.
- The SPRINT trial was stopped after 3 years because it was so successful at reducing cardiovascular mortality, which will often show a more immediate effect than longer-term impacts on cognition and the brain. It is useful to consider not only mortality but function and independence, which is a primary concern for patients.
- Dr. Williamson spoke to the need for medical associations to adjust their recommendations related to treatment of hypertension based on recent findings

and for people to “own” their own health care. There must be a partnership between people and their physicians.

ACHIEVE Intervention for Hearing Loss

Frank R. Lin, MD, Johns Hopkins Bloomberg School of Public Health

Hearing loss in mid-life and late-life is a significant risk factor for dementia. Hearing loss may contribute to dementia through the following mechanisms: (1) by sending more “garbled” information to the brain, thus taxing its system; (2) through accelerated rates of brain atrophy caused by reduced auditory stimuli; and (3) indirectly, through the social isolation that may result from hearing loss. Likely a combination of these three factors is involved. Observational studies have indicated that hearing aid use is associated with a decreased risk of cognitive decline, but it was not known whether this is because hearing aid use is more common among healthier and wealthier individuals.

The Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study is the first RCT to examine the question of whether treating hearing loss can reduce cognitive decline.

ACHIEVE is a collaboration across eight universities, funded by NIA. It examines cognitive decline over 3 years among 1,000 older adults ages 70-84 with a typical level of hearing loss and normal cognition. Treatment involved hearing aid use and regular sessions with an audiologist. Participants were tested every 6 months with a battery of neurocognitive tests. Some study subjects came from another study, ARIC, and represent a random sample of the population. Other participants were recruited from Facebook ads; these participants had many fewer baseline risk factors for cognitive decline. Findings indicate that among the participants with typical risk factors for dementia, the hearing intervention reduced cognitive decline by 48% as compared to a control group. Participants with lower risk factors showed a much slower rate of cognitive decline in general, and therefore did not have a significant reduction in cognitive decline.

These findings are important information for NAPA partner agencies because hearing interventions can substantially reduce cognitive decline but are underused. Government action is needed to provide insurance coverage for hearing interventions, though the recent over-the-counter (OTC) availability of hearing aids is also expected to drive innovation and affordability. Public awareness of this issue is also important.

Discussion

- There is stigma with hearing impairment and with the use of hearing aids.
- With hearing aids going OTC, more marketplace innovation is expected. For example, there are glasses being developed that work as hearing aids. This can help change the dynamic around stigma.
- People who volunteered for the study were already self-selecting as willing to use hearing aids, but even for this group, continued involvement from an audiologist is important in supporting continued use. Audiologists have to be incentivized to regularly follow up. This is both a lifestyle and medical intervention.

- Yakeel Quiroz asked Dr. Lin about any gender differences in the study. Pre-menopausal women have less hearing loss; estrogen has a protective effect on inner ear. Dr. Lin indicated that they have not seen significant differences in effect sizes by gender.
- Helen Bundy Medsger asked about the benefits of treating hearing loss in addressing confusion, agitation, and other behavioral symptoms in people living with dementia. Dr. Lin spoke to research that is occurring or has occurred on secondary and tertiary prevention, for people with mild cognitive impairment (MCI) or people who already have dementia. There is evidence that addressing hearing problems can improve communication between people living with dementia and caregivers.

EXERT Exercise Intervention and U.S. POINTER Multivariate Intervention

Laura D. Baker, PhD, Wake Forest University School of Medicine

Dr. Baker shared information about two non-pharmacological interventions to reduce cognitive decline. The first is an intervention called EXERT (Exercise in Adults with Mild Memory Problems), funded by the NIA. Researchers partnered with YMCAs at 14 sites around the United States to deliver an exercise program over a period of 12 months. Previously sedentary participants with MCI exercised under supervision four times a week at either high or low intensity and were compared with those who did not exercise. The treatment group showed no cognitive decline over 12 months, while the control group did decline. There was no difference in cognitive outcomes among the high-intensity versus low-intensity exercise groups. The finding is that any regular exercise of 120-150 minutes per week may increase resistance or resilience to cognitive decline for people with MCI.

The United States Study to Protect Brain Health Through Lifestyle Intervention to Reduce Risk (U.S. POINTER) intervention is a separate study, related to the Finnish Geriatric Intervention Study to Prevent Cognitive Impairment and Disability (FINGERS) studies taking place internationally. It is supported by the Alzheimer's Association and addresses multiple lifestyle factors. Two thousand cognitively normal but at-risk adults (sedentary with poor diet, family history of memory problems, cardiac risk factors, or racial/ethnic risk factors) will participate in a structured lifestyle coaching group, including exercise, nutrition, cognitive exercise, and medical monitoring. Participants will meet with their peer groups for 2 years. This study is in its early stages; enrollment is complete and includes representation from communities of color and those with other risk factors such as lower educational attainment. The study will conclude in summer 2025, with results expected in fall 2025.

Discussion

- Dr. Baker mentioned the importance of how research participants are recruited. POINTER used extensive community outreach to find participants who would typically have been left out of research in the past.
- Sustainability is also key. Once the EXERT trial results are published, the YMCA is planning a national conference to discuss how to continue the work EXERT

started through the YMCA system, and researchers are already in conversation with the Alzheimer's Association about mechanisms to help sustain these programs.

- There was a question about strength training versus cardiovascular fitness. In EXERT, the primary focus was on cardio-respiratory fitness. But in POINTER, part of the structured intervention is on strength training. Falls prevention is also important and involves stretching and strength.
- POINTER was provided in both English and Spanish.

LatAm FINGERS Multivariate Intervention in Latin America

Lucia Crivelli, PhD, FLENI Foundation, Buenos Aires, Argentina

The Latin American FINGERS intervention, like U.S. POINTER, is supported by the Alzheimer's Association. Twelve countries are participating in the trial, including Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Mexico, Peru, Puerto Rico, and Uruguay. The goal is to investigate the feasibility and efficacy of a multi-faceted intervention in these countries. The intervention provides guidance and support to participants on exercise, nutrition, and cognitive stimulation through health coaching; the control group receives health advice. Participants are at risk for dementia; 39% have metabolic syndrome, although the specific risk factors vary significantly from one country to the next. The researchers have adapted the interventions to be culturally friendly and feasible. For example, they are tailoring the nutrition information to the typical diet and available foods in each area.

Discussion

- The learnings about adapting FINGERS to different cultural audiences will be important when considering how to adapt interventions to different populations in the United States.

Messaging Campaign

Kay Deckers, PhD, Maastricht University, Netherlands

This Dutch public health awareness campaign -- "We are the medicine ourselves" -- aimed to increase public awareness of dementia risk factors and the fact that they can be modified. It was launched in March 2018 and lasted through January 2019, in the southern Netherlands, targeting individuals between 40-75 years old. The campaign emphasized three messages: (1) stay curious (hobbies, learning, social life); (2) eat healthy (fruits, vegetables, fish, olive oil); and (3) exercise regularly (walking, biking, swimming). Campaign materials were reviewed by a panel of people living with dementia, their caregivers, and other stakeholders. An App, "My Brain Coach", provided users with daily insights into the areas where they were doing well and areas for improvement. They used campaign events and outreach to local officials and businesses to help spread the word. Pre-surveys and post-surveys of random participants showed increased awareness across all three topics, particularly diet and

exercise. A booster awareness campaign is planned for 2024, and the developers are supporting other areas in the Netherlands and Europe by sharing their materials.

Overview of National Alzheimer's Project Act Implementation

Helen Lamont, PhD, ASPE

Helen Lamont provided a brief history of the National Alzheimer's Project Act (NAPA) law signed in 2011 and the Advisory Council it established. The council is unique in having both federal and non-federal members and includes representation of different types of dementia and geographic diversity across the United States. The National Plan is updated annually to summarize completed, current, and planned work. HHS and its federal partners meet regularly to collaborate and coordinate efforts.

The non-federal committee members make recommendations to the Secretary of HHS and Congress as well as to states and other applicable bodies. The federal members of the Advisory Council cannot provide advocacy but can advise public members. The 2023 Advisory Council recommendations were recently posted on the ASPE website. The latest National Plan is expected to be released in November or December 2023.

Most Advisory Council work takes place through its four subcommittees: (1) Research (Randall Bateman, Chair); (2) Clinical Care Chair TBD); (3) Long Term Services and Supports (Helen Bundy Medsger, Chair); and (4) Risk Reduction (Joanne Pike, Chair).

Agency Progress

Representatives of federal agencies provided updates on progress made since NAPA was passed and specifically highlighted work in the past quarter:

Richard Hodes, MD, NIA

The NIA leads federal research efforts on Alzheimer's disease and related dementias (AD/ADRD) related to prevention and treatment, care and support, biomarkers, disease mechanisms, and more. Through multiple rotating annual summits that convene subject matter experts and stakeholders, research gaps and opportunities are identified, and research implementation milestones are developed. Since 2015, there has been a six-fold increase in funding for research on the major causes of dementia. Scientists have learned that there are mixed pathologies involved in most dementias and have identified 70 genetic variants linked to dementia, compared to ten known 10 years ago. Upcoming activities related to dementia research include: a Cognitive Aging Summit in March 2024; an NIH ADRD Research Summit in September 2024; and a National Academies of Sciences, Engineering, and Medicine task force report on research priorities for preventing and treating AD/ADRD, anticipated in early 2025.

Walter Koroshetz, MD, National Institute of Neurological Disorders and Stroke (NINDS)

NINDS is funding AD/ADRD research related to the pathologies of Frontotemporal Degeneration (FTD), Lewy Body Dementia, and vascular dementia. Several different NINDS programs focus on targets like identifying biomarkers, increasing detection in primary care settings, molecular mechanisms of the disease, stroke types and co-morbidities, and REM sleep behavior disorder's connection to dementia. NINDS is also studying people who have risk factors for but do not develop dementia and have found that some rare gene variants provide resilience against dementia, which has potential for future therapies.

Teresa Buracchio, MD, Food and Drug Administration (FDA)

Note: The May 2023 NAPA Advisory Council meeting included a detailed presentation on FDA's role. [Available at <https://aspe.hhs.gov/sites/default/files/documents/0bd9bc140e1774254d7e0081db27c9ef/napa-may-2023-buracchio.pdf>]

FDA is responsible for protecting the public through the safety of human and veterinary drugs, safety of food and cosmetics, and safety of products that emit radiation. In 2021, the FDA approved aducanumab, a new medication for the treatment of AD/ADRD, through the accelerated approval pathway and in 2023, it gave full approval to lecanemab, also to treat AD/ADRD. The FDA has also approved new diagnostic products, including cerebral-spinal fluid-based diagnostics, tau-PET imaging agents, and amyloid-PET imaging agents.

Shari Ling, MD, and Ellen Blackwell, CMS

CMS is the single largest purchaser of health care in the United States. It serves nearly one-half of Americans in the health care marketplace and plays a key role in transitioning the health care system from fee-for-service to value-based care. Almost 64 million Americans receive Medicare, and nearly 75 million receive Medicaid; more than 12 million are "dual-eligible", participating in both programs. This population tends to have high rates of chronic conditions and often is diagnosed with multiple conditions.

Many decisions about Medicare and Medicaid coverage are made at the local level, but some recent national decisions impacting dementia care have included developing payment codes to support cognitive screening as part of Medicare Annual Wellness Visits, removing limits on the number of PET scans that can be covered (which can help diagnose AD/ADRD), and coverage of new treatments like the drug Leqembi. Additional changes to fee schedules for physicians are anticipated, including those that provide coverage for caregiver training.

Health care innovation awards have permitted states to experiment; these projects have led to the GUIDE model now being rolled out by CMS. Other CMS activities that relate to dementia care include the Medicare-Medicaid Coordination Office, which works to coordinate benefits between the two programs; the Center of Excellence for Behavioral

Health in Nursing Facilities, established in 2022 in partnership with the Substance Abuse and Mental Health Services Administration (SAMHSA); Civil Money Penalty Funds, which states are often choosing to target to dementia programs; cognitive impairment and care planning codes being rolled out by CMS to cover dementia supportive services; and Hand in Hand, a CMS training series for direct care workers in nursing homes to learn person-centered care approaches for persons with dementia.

Bruce Finke, MD, IHS

The IHS is responsible for providing federal health services to 2.6 million American Indian and Alaskan Native individuals in 37 states through a system of hospitals, health centers, Tribally operated health care systems, and the Urban Indian Health Program. In 2021, through the work of NAPA, the IHS received funding to support an initial cohort of tribes, Tribal organizations, and urban Indian organizations to develop comprehensive models of care and services for dementia; to develop the dementia workforce; to conduct outreach and awareness activities; and to provide related data and program support. A goal of this program is to learn what works in Tribal communities and what needs to be adapted.

Within the focus area of workforce development, there is work to do in building capacity. This includes efforts such as the Indian Country ECHO programs in clinical care and caregiver support; Indian Health Geriatric Scholars; the Early Dementia Detection Initiative; and the Geriatric Emergency Department Accreditation Initiative within the IHS Division of Nursing Services.

Joan Weiss, PhD, RN, HRSA

Through the Geriatric Workforce Enhancement Program, over 6,000 interprofessional dementia education trainings have been provided to more than 700,000 participants. HRSA also developed a 16-module curriculum on dementia care and nine modules on caregiving, available on the HRSA dementia webpage. It has recently overseen the creation of a multi-media, multi-module nursing home training, which will be available on HRSA's dementia webpage once finalized.

Erin Long, MSW, ACL

ACL was established in 2012, when the Administration on Aging (AoA), the Office on Disability, and the Administration on Developmental Disabilities merged. The AoA funds the Alzheimer's Disease Programs Initiative (ADPI), which supports state agencies and community-based organizations in expanding dementia-capable home and community-based services and supports. Many types of organizations are funded through ADPI, including universities, hospice and palliative care organizations, health care systems, Area Agencies on Aging, and community-based organizations. Grantees pilot and evaluate programs and share processes and products developed as well as lessons learned. All ADPI grants are required to implement an evidence-based or evidence-informed intervention. The National Alzheimer's and Dementia Resource Center (NADRC) provides technical support to ADPI grantees and to dementia professionals.

Since the last NAPA Advisory Council meeting, 18 state and community grants have been awarded. Additionally, two new resources are available -- one on promising programs for people living alone with dementia, and one on addressing social isolation and loneliness among people living with dementia and their caregivers. A webinar on the National Strategy to Support Family Caregivers was planned for Wednesday, November 1; recordings of webinars are available through the NADRC website.

Arlene Bierman, MD, MS, AHRQ

The goal of AHRQ is to produce evidence to make health care safer, more equitable, accessible, affordable, and better quality. It funds health services research to understand how care is delivered and how to improve delivery. This includes improving person-centered care planning and services, which elicits individuals' values and preferences and uses those to guide care.

On April 14, 2023, AHRQ convened a roundtable of about 40 multidisciplinary experts to discuss how AHRQ can support improved organization and delivery of health care to the aging United States population. A report, *Optimizing Health and Function as We Age*, is available.

Eric Weakly, MSW, MBA, SAMHSA

SAMHSA was established in 1992 and leads public health efforts to advance behavioral health. It funds providers, community organizations, and states. It implements the nationwide 988 suicide prevention line and develops many products related to serving older adults, including those with cognitive impairment. The Center of Excellence for Behavioral Health Disparities in Aging will examine the intersection of dementia, substance abuse, and other mental health issues in its work this year.

Lisa McGuire, PhD, CDC

The CDC's aim is to protect the health, safety, and security of the United States by detecting and responding to new and emerging health risks, tackling leading causes of death and disability, and putting science and technology into action. It serves as a convener and connector, bridging the gap between biomedical research and community services. AD/ADRD programs fit within the CDC's National Center for Chronic Disease Prevention and Health Promotion.

Since the passage of NAPA, funding for dementia work at the CDC has increased by over 1,000%. The CDC has produced three public health roadmaps for dementia, including the first one for Indian Country. Through the passage of the BOLD Act, the CDC has funded three Public Health Centers of Excellence and two cycles of grant awards, totaling 66 3-year and 5-year grant programs. It has expanded Healthy Brain Initiative Awards from one to five awards, launched the Healthy Brain Resource Center, and created an ADRD data portal with state-level and national-level data infographics. The BOLD Centers have developed state-specific fact sheets on the prevalence of six dementia risk factors. In addition, the CDC has many free, downloadable materials that integrate messages about AD/ADRD into other chronic disease information.

Sarah Fontaine, PhD, DOD

The Congressionally Directed Medical Research Programs include 35 programs funding biomedical research, focusing on health care solutions that benefit service members, veterans, their beneficiaries, and the American public. Its Peer-Reviewed Alzheimer's Research Program (PRARP) started in 2011 with a goal of understanding why service members are at elevated risk for dementia. To date, PRARP has funded 168 awards totaling \$147 million. In fiscal year 2022, it funded 16 awards related to epidemiology, biomarker validation, and diagnostics. This work involves an advisory panel of people with lived experience.

Rebecca Ferrell, PhD, NSF

The NSF was formed in 1950 to fund fundamental research in science and engineering. It does not have a specific AD/ADRD area of focus, but it has had a large portfolio of dementia-relevant research totaling \$223 million across 498 awards.

Public Comments

- **Susan Peschin**, Alliance for Aging Research, requested that CMS consider revising its guidance on use of antipsychotics in nursing homes. Use of antipsychotics is not necessarily tied to insufficient staffing levels; staff are trained to use non-pharmaceutical approaches first when addressing behavioral challenges among residents. Nursing home staff must be able to prescribe medications for symptoms like extreme agitation when needed, with documentation of why and how the medications were prescribed. CMS does not collect data on people who have been forced to move out of facilities due to extreme behavioral issues, but this can be one outcome if practitioners cannot use tools like antipsychotics.
- **Jessica Copeland**, National Center for Health Research, encouraged the Advisory Council to develop an advocacy campaign to educate the public on cognitive impairment. Dementia and MCI can have many causes outside of AD/ADRD, some of which are treatable. Public awareness is important to reducing fear and anxiety as well as unnecessary medical treatment.
- **Michael Rafii**, Professor of Neurology at the University of Southern California Keck School of Medicine, shared that the fastest growing segment of the Down syndrome population is people over the age of 50. AD/ADRD is now the leading cause of death for people with Down syndrome over the age of 35. However, people with Down syndrome have been excluded from clinical trials for amyloid treatments. There is a need for collaboration and much greater inclusion of this population in research and clinical trials.
- **Susan Eissler**, volunteer ambassador for the Association for Frontotemporal Degeneration, spoke of the importance of improved public awareness of FTD symptoms, including among primary care physicians. Both her husband and son developed and died from FTD. This is a disease that generally impacts people at

younger ages, and symptoms generally relate to judgment, behavior, and executive functioning. There is currently no treatment, and it is difficult for caregivers to know where and how to access information from the various available sources. In addition, there needs to be greater opportunity for people with FTD to engage in behavioral interventions.

- **Hasan Shah**, National Down Syndrome Society, advocated for representation of people with Down syndrome on the NAPA Advisory Council. Because AD/ADRD is the leading cause of death for people with Down syndrome, this population must be included in annual NAPA recommendations. Further, Mr. Shah recommended an Advisory Council subcommittee focused on issues and solutions for people with IDD, including Down syndrome. Key topics for people with Down syndrome include access to clinical care, increased support for research, access to treatment and clinical trials, and access to services and supports.

Concluding Remarks

Dr. Mims thanked presenters and council members and noted that the next meeting will be held January 23, 2024.

The meeting adjourned at 4:28 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>.