

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

Virtual Meeting

May 2-3, 2022

Advisory Council Members in Attendance

- *Non-Federal Members Present:* Cynthia Carlsson (Chair), Randall Bateman, Venoreen Browne-Boatswain, Matthew Janicki, Ken Kim, Helen Bundy Medsger, Adrienne Mims, Joe Montminy, Maria Ortega, Joanne Pike, Rhonda Williams
- *Federal Members Present:* Teeb Al-Samarrai (Office of the Surgeon General), Kim Wittenberg substituting for Arlene Bierman (Agency for Healthcare Research and Quality, AHRQ), Ellen Blackwell (Centers for Medicare & Medicaid Services, CMS), Bridget Burke (AHRQ), Roderick Corriveau (National Institute of Neurological Disorders and Stroke, NINDS), Rebecca Farrell (National Science Foundation, NSF), Bruce Finke (Indian Health Services, IHS), Sarah Fontaine (Department of Defense), Richard Hodes (National Institutes of Health, National Institute on Aging, NIH/NIA), Shari Ling (CMS), Erin Long (Administration for Community Living, ACL), Lisa McGuire (Centers for Disease Control and Prevention, CDC), Cheryl Schmitz (Department of Veterans Affairs, VA), Tisamarie Sherry (Department of Health and Human Services/Office of the Assistant Secretary for Planning and Evaluation, HHS/ASPE), Eric Weakly (Substance Abuse and Mental Health Services Administration, SAMHSA), Joan Weiss (Health Resources and Services Administration, HRSA)
- *Quorum present?* Yes
- *Advisory Council Designated Federal Officer:* Helen Lamont (ASPE)

DAY 1

General Proceedings

Chair Cynthia Carlsson called the meeting to order at 1 p.m. Eastern Daylight Time.

Federal Agencies 10 Years of Accomplishments

“National Plan to Address Alzheimer’s Disease: Celebrating 10 Years”

Tisamarie Sherry, MD, PhD, Deputy Assistant Secretary, Office of Behavioral Health, Disability, and Aging Policy, ASPE

- The National Alzheimer’s Project Act requires developing a National Plan to overcome Alzheimer’s disease and related dementia (AD/ADRD); coordinating research and services across all federal agencies; accelerating treatment development; improving early diagnosis, care, and care coordination; coordinating with international organizations; and convening the Advisory Council on Alzheimer’s Research, Care, and Services.
- **Richard Hodes (NIH)** described key NIH accomplishments, including support for breakthrough research on biomarkers, genetics underlying ADRD, and links between lifestyle choices and ADRD. NIH also supports several consortia and collaborative groups with accomplishments that include developing approaches for recruiting members of minority populations to participate in clinical trials and for addressing care management challenges.
- **Rebecca Ferrell (NSF)** explained that NSF funds basic research on dementia, research to advance diagnostics and treatment, and research to improve quality of life for people living with dementia and their caregivers. Accomplishments include research on amyloid properties; the digital clock test to detect early, subtle impairment; a project exploring use of artificial intelligence in robotic pets to assess and assist with challenges of daily living; and development of culturally relevant tools to decrease burden among African American caregivers.
- **Cheryl Schmitz (VA)** said that VA has sponsored 18 research initiatives and published 59 articles on ADRD over the past 10 years. Highlights include adopting the Kern curriculum to guide development and evaluation of training materials; purchasing and disseminating Hand-in-Hand training for Community Living Centers; deploying virtual dementia simulation for acute care providers; updating Dementia Steering Committee recommendations; recognition of the Madison, Wisconsin VA Medical Center as the first dementia-friendly VA facility; the Caring for Older Adults and Caregivers at Home (COACH) program earning a Veterans Health Administration Gold status practice award; developing and launching the Annie Caregiver text program; launching the Dementia Education Portal; and launching the National Template of dementia warning signs.
- **Joan Weiss (HRSA)** reported that the Geriatrics Workforce Enhancement Program (GWEP) has offered 5,383 opportunities for education about dementia to 687,048 trainees since 2012. HRSA developed an online ADRD continuing education curriculum for health care providers. More than 9,000 users have earned certificates. HRSA offers a caregiving curriculum for providers with modules about caregivers’ needs and teaching caregivers coping and self-care skills. In

collaboration with the John A. Hartford Foundation, Institute for Healthcare Improvement, and American Geriatrics Society, HRSA is supporting GWEP efforts to teach primary care practitioners how to deliver age-friendly health care. In fiscal year 2021, HRSA collaborated with ASPE to develop a report on current capacity of dementia specialists for Congress.

- **Ellen Blackwell (CMS)** described accomplishments of the National Partnership to Improve Dementia Care in Nursing Homes, including promoting person-centered non-pharmacological interventions and reducing antipsychotic medication use by approximately 40%. CMS and SAMHSA are sponsoring a cooperative agreement to establish the Center of Excellence for building capacity in nursing facilities to care for residents with behavioral health conditions.
- **Bruce Finke (IHS)** reported that IHS provides direct care services and collaborates with CMS and ACL to offer technical assistance for long-term services and supports. IHS collaborated with several organizations to pilot test caregiver support and coaching for Tribal communities. IHS collaborates with the VA to deliver Rural Interdisciplinary Team Training, including Addressing Behavioral Challenges in Dementia, at rural IHS and Tribal sites. IHS worked with the CDC to develop and disseminate the *Healthy Brain Initiative Roadmap for Indian Country*, and infographic publications. Current efforts include working with Northwest Portland Area Indian Health Board to launch a Dementia ECHO for clinicians and caregivers.
- **Kim Wittenberg (AHRQ)** reported that AHRQ has funded or conducted Evidence-based Practice Center reviews related to ADRD. These include a summary of evidence on dementia diagnosis and treatment, non-pharmacologic interventions for dementia-related agitation and aggression, characteristics of residential care settings associated with improved health and psychosocial outcomes for people with dementia, assessing evidence for effectiveness of care interventions, and effectiveness of prevention efforts. AHRQ funds several grant mechanisms to support improving dementia care.
- **Erin Long (ACL)** said that ACL prioritizes addressing the needs of people who live alone with dementia, people living with intellectual or developmental disabilities and dementia and their caregivers, and behavioral symptoms of dementia. ACL has funded 157 grants to states and communities since 2013. Grantees implement evidence-based and evidence-informed interventions. Programs have served more than 35,000 people living with dementia and more than 54,000 caregivers. Grantees have trained more than 97,000 professionals. ACL funding has supported more than 2 million direct service hours.
- **Lisa McGuire (CDC)** presented highlights of accomplishments including support for the Healthy Brain Research Network, fielding measures of cognition in the National Health and Nutrition Examination Survey (NHANES), publishing Healthy Brain Initiative road maps for state and local public health agencies, producing a

Healthy People 2020 Progress Review on older adults and dementias, adding cognitive decline and caregiving modules to the Behavioral Risk Factor Surveillance System (BRFSS), and developing and disseminating infographics and a newsletter. The Building Our Largest Dementia (BOLD) Infrastructure Act authorizes CDC to establish Alzheimer's disease Centers of Excellence, provide funding for public health departments, and expand data analysis and timely reporting.

- **Tisamarie Sherry (ASPE)** reported that ASPE has conducted work to identify people living with dementia, measure the population of people with dementia, identify the unique care needs of people with dementia, and study ADRD disparities. ASPE supported the first National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers. ASPE will publish an issue brief on federal efforts to address ADRD disparities. ASPE also supports the Advisory Council and annual updates to the National Plan.

“Overview and Clinical Perspectives”

Shari Ling, MD (CMS)

- CMS’s vision for the next 10 years is “a health system that achieves equitable outcomes through high quality, affordable, person-centered care.” CMS aims to support longer life and improved functioning/participation, arrested decline, reduced need for burdensome tests and treatments, and clinician confidence.
- Nearly all people with Alzheimer’s disease have at least one other chronic condition; more than half (54%) have at least four additional chronic conditions.
- In 2014, Congress enacted the Improving Medicare Post-Acute Care Transformation (IMPACT) Act, which requires facilities to submit to CMS standardized and interoperable patient assessment data elements, including some related to cognitive functioning, in order to facilitate coordinated care and improve health outcomes.
- CMS pays for many dementia diagnostic and care services, including cognitive assessments. On April 7, 2022, CMS made a national coverage determination to pay for Food and Drug Administration (FDA)-approved monoclonal antibody treatment against amyloid for patients who have mild cognitive impairment or dementia due to Alzheimer’s disease, and who have confirmed amyloid beta pathology consistent with Alzheimer’s disease.

Panel Discussion: Biomarkers and Therapeutics

"NAPA Scientific Research Subcommittee: Scientific Advances to 2025 Goal"

Randall Bateman, MD, Professor of Neurology, Washington University in St. Louis School of Medicine

- Neuritic amyloid-beta plaque and neurofibrillary tau tangles are underlying pathologies of Alzheimer's disease. Amyloid plaques typically accumulate for 15 years prior to symptom onset and reach maximum accumulation approximately at the same time that symptoms begin. Hypometabolism, atrophy, and shrinkage continue over the course of the disease. Diagnosis and treatment prior to symptom development is critical.
- Researchers are working to develop drugs that can change the course of Alzheimer's disease. Current challenges include identifying the right targets for treatment, determining appropriate dosage and frequency, and determining when to begin treatment. Recent trials treat people prior to symptom onset. One study found that gantenerumab reduced asymptomatic patients' amyloid plaque to near normal levels and significantly reduced amyloid plaque for symptomatic patients. The drug also reduced tau and neurofilament light chain levels, which indicate neurodegeneration. Research is necessary to determine clinical benefits. Dr. Bateman encouraged consideration of how to accelerate delivery of research advancements to patients.

"Fluid Biomarkers of Alzheimer's Disease"

Suzanne E. Schindler, MD, PhD, Associate Professor of Neurology, Washington University in St. Louis School of Medicine

- Alzheimer's disease is defined not by symptoms but by the presence of biomarkers. These biomarkers indicate whether dementia is caused by Alzheimer's disease and also serve as indicators of treatment effects. Clinicians rarely use biomarkers for diagnosis because current appropriate use criteria recommend use for atypical, early onset, and uncertain dementia. Biomarker confirmation of Alzheimer's disease is essential before initiating amyloid decreasing drug treatment. As these drugs become more available, biomarker diagnosis must increase.
- Cerebrospinal fluid biomarkers can diagnose multiple conditions. Insurance payers usually reimburse most of the test cost but do not adequately reimburse providers for the time required to administer the test. Clinicians find the test burdensome, and patients, especially those from underserved minority populations, perceive spinal taps to be invasive and can experience headaches and back pain as a result of the test. Patients prefer blood biomarker tests. Insurance does not currently cover the cost (approximately \$1,250). Only one blood test is currently available. Researchers currently are developing several plasma biomarker assays.

- Biomarker levels associated with brain amyloidosis or symptomatic Alzheimer's disease may vary with several individual-level factors, including demographics and Apolipoprotein E (APOE) genotype. Most thresholds for biomarker positivity have been defined based on research samples of mostly educated non-Hispanic White participants. Research is needed to assess the accuracy of the tests for diverse populations.
- Many asymptomatic older adults have significant Alzheimer's disease pathology. Additional research is needed to determine whether a person with Alzheimer's disease pathology is likely to develop symptoms and when these symptoms would be likely to develop.
- Because very few patients get biomarker tests, misdiagnosis is common. Lack of insurance coverage for blood biomarker tests is currently the most important barrier to testing. The factor most likely to overcome this barrier is approval for more treatments for Alzheimer's disease, which are likely to require biomarker testing. Only blood tests have the potential to screen a large number of patients when more drug treatments are approved.

"Imaging Biomarkers for Alzheimer's Disease"

Gil Rabinovici, MD, Professor, Director, Alzheimer's Disease Research Center, University of California, San Francisco

- The FDA approved PET scan tests based on research showing that results demonstrate high sensitivity and specificity when compared with autopsy data on brain pathology. PET images show the presence of amyloid plaques and neurofibrillary tangles in the brain, allowing researchers to monitor Alzheimer's disease evolution in living people. Nearly all people develop tau tangles in their medial lobes by age 50 years. Amyloid plaque reaches an early plateau and promotes spread of tau tangles. Spread of tau tangles is associated with cognitive impairment.
- The Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) study collected amyloid PET data on a national sample of adults older than 65 years who had mild cognitive impairment or dementia in order to assess the impact of scanning on patients' medical plans and major medical outcomes. Diagnosis changed for more than one-third of patients. Patient management changed for 60% of patients with mild cognitive impairment and 64% of patients with dementia. PET was associated reduced hospitalizations but not emergency department visits over the subsequent 12 months. Results suggest PET scans meet CMS criteria for coverage, although CMS does not currently cover this procedure.
- The New IDEAS project will recruit a sample of 7,000 Medicare beneficiaries with typical or atypical Alzheimer's disease who represent groups traditionally underrepresented in clinical trials for researcher on genetic and plasma biomarkers.

- PET scans are used to validate blood tests of biomarkers. They support accurate patient selection for clinical trials, early clinical intervention, and determining the level of target engagement. Advances in biomarkers are likely to support development of novel therapies and a shift from treating symptoms to early detection and disease prevention.

“Emerging Experimental Therapeutics in Alzheimer’s Disease: Monoclonal Antibodies to Amyloid and Beyond”

Alireza Atri, MD, PhD, Director, Banner Sun Health Research Institute

- Currently available fully approved drugs treat only Alzheimer’s disease symptoms. Only aducanumab treats underlying causes, but its clinical benefits remain uncertain. Aducanumab is a second generation monoclonal antibody, which was given accelerated FDA approval based on evidence that it reduces beta-amyloid plaques in patients. This may result in modest slowing of disease progression. Both major studies of aducanumab have shown that the drug reduces amyloid plaques and may impact plasma tau, and that side effects such as amyloid-related imaging abnormalities (ARIA) can be managed effectively with strict safety protocols.
- Research on multiple second generation monoclonal antibody treatments shows that increased amyloid plaque removal is associated with increased clinical benefit. Stakeholders must consider which risks and benefits are reasonable to expect from Alzheimer’s disease treatments. Policy makers must consider how to define “reasonably likely to predict clinical benefit,” “clinically meaningful outcome,” and “reasonable and necessary” for patients with pathology associated with Alzheimer’s disease. Researchers must assess which biomarkers affect benefits and safety, and how. Clinicians need practical guidance on how to translate research findings into practice.
- Accelerated approval is provided for treatments without definitively proven clinical benefits, but which affect biomarkers that could reasonably predict clinical benefit for patients with serious conditions for which treatment needs are not met. Because FDA approval was accelerated, CMS only pays for cost of monoclonal antibody treatment for patients participating in FDA or NIH-approved trials.

Discussion

- Dr. Mims asked whether the changes in diagnoses from Alzheimer’s disease to non-Alzheimer’s disease found in Dr. Rabinovici’s study were primarily to other forms of dementia or to non-dementia, and whether therapeutic changes were primarily due to using other drugs targeting dementia. Dr. Rabinovici said the main change was attribution of the cause of dementia. The most common therapeutic change was to stop prescribing drugs specifically targeting Alzheimer’s disease. PET scans can help to resolve uncertainty about diagnosis and degree of concern for patients with mild cognitive impairment and their families. Dr. Mims said

knowing specific causes of symptoms has limited value to primary care providers; it will be useful to learn how to improve patient outcomes 10 years in advance. Dr. Bateman said many current studies are focused on this goal. Drs. Schindler and Atri said patients sometimes want to know their diagnosis so that they can decide how to spend their time, choose whether to participate in a clinical trial, and avoid risks of treatment not appropriate for their condition. Dr. Rabinovici said biomarker tests can help these patients.

- Ms. Medsger said biomarker tests provide information about whether a condition is linked to a family's genetics and should be available on demand for this purpose. She called for educating the public about the tests and for increasing their accessibility.

DAY 2

Progress Update: Dementia Nomenclature Initiative

Angela Taylor, Lewy Body Dementia Association

Ron Peterson, MD, PhD, Mayo Clinic

- Several issues inspired formation of the nomenclature steering committee: (1) Patients often ask providers to explain the difference between Alzheimer's disease and dementia; (2) "Dementia" and related terms are sometimes associated with stigma; (3) It is important for researchers to be clear regarding whether they are referring to only underlying pathology or a combination of underlying pathology and symptoms when they use the term "Alzheimer's disease;" (4) Efforts to promote public health rely on clear and culturally sensitive communication; and (5) Poor communication about dementia can result in stigma, delays in diagnosis and care, barriers to effective public education, and confusion in public policy and research.
- The Council formed a nomenclature steering committee that includes research, clinical care, and public stakeholder working groups. All groups were charged with identifying words and terms to describe the full spectrum of cognitive impairment. The research working group was asked to develop a standard framework for communications. The clinical care working group assesses needs to improve terminology in order to support clinical management. The public stakeholders working group assesses cultural sensitivity issues related to terminology.
- The current framework defines diseases by clinical presentation, which is defined by clinical features, age of onset, severity range of clinical features, and overall functional impact. Clinical features are categorized as cognitive, behavioral/psychiatric, motor, and other neurologic symptoms. Disease definition includes the cause of clinical presentation. Evidence of cause includes biomarkers, genetic mutations, and autopsy confirmation. A review of clinical presentation and evidence of cause supports diagnosis, understanding, and clear communication.

- The committee is in the process of determining an umbrella term for the diseases/disorders in its purview. Criteria for the umbrella term are that it must describe all diseases/disorders of concern while distinguishing them from others, be understandable to the public, be useful for researchers and clinicians, and have the potential to mitigate stigma. Candidates are “adult cognitive diseases” and “adult cognitive disorders.” The committee currently favors “adult cognitive diseases,” which is an appropriate term because of the underlying biological factors. However, several diseases not in the committee’s purview, such as traumatic brain injury, can be included in this category.
- Focus groups with diverse stakeholders provided feedback on the communication framework. Participants emphasized the importance of ensuring the framework can be used in electronic health records and other health databases as well as policies such as the NAPA plan. Participants agree that the proposed framework will clarify communication and also support workflow, care planning, and drug development.
- The next phase of the subcommittee’s work is to solicit more input on the communications framework; build consensus among multiple groups of stakeholders, including professional societies and journal editors; beta test the framework in clinical settings; and develop tools to facilitate uptake of the framework.

Discussion

- Ms. Medsger noted that several international groups are exploring dementia nomenclature issues and asked whether the steering committee had considered these. Presenters confirmed that the steering committee has consulted with international colleagues and will continue to do so.
- Dr. Finke said “conditions” is typically the term used for syndromes rather than “disease,” suggesting this is the better terms for ADRD. Dr. Peterson said “syndrome” refers to clinical impairment and it is important to address the underlying pathology of ADRD at preclinical phases, which suggests that “disease” is the better term.

Panel Discussion: Risk Reduction

“Measuring and Assessing Progress Toward Goal 6”

Tisamarie Sherry, MD, PhD, ASPE

- Research has provided evidence about risk factors for dementia. The strongest evidence supports reducing risk through effective management of hypertension. There is encouraging evidence for reducing risk through physical activity and cognitive training, and emerging evidence about risks associated with inadequate sleep, poor nutrition, hearing difficulties, depression, substance use disorders, and oral health. In light of this evidence, the Council recommended adding a risk

reduction goal to the National Plan in July 2021; HHS accepted this recommendation and added the goal in December 2021.

- The Council should consider how to define progress toward achieving this goal. The Council should consider how to determine whether federal risk reduction activities result in improved brain health and healthy aging, how strength of evidence guides the focus of measurement efforts, how to measure progress toward decreasing disparities, and whether additional data infrastructure is necessary to measure progress accurately. HHS would like a framework for identifying and improving measures, tracking disparities, identifying needs for infrastructure enhancement, and determining how to review progress and update the measurement plan.

“The Public Health Center of Excellence on Dementia Risk Reduction”

Matthew Baumgart, Vice President of Health Policy, Alzheimer’s Association

- The Center collaborated with Wake Forest University research to review and synthesize population-level evidence about modifiable risk factors for cognitive decline and dementia, and published summary reports about risk factors and the public health implications. The Center is developing tool kits and other resources for public health agencies. The Center also is analyzing state and local data on risk factors to help public health agencies prioritize efforts. It has published suggestions for risk reduction recommendations to include in state and local plans. The Center also convenes community stakeholders to determine plans of action.
- In August 2021, the Center hosted a public health roundtable with academics and state officials to identify and prioritize public health actions to address risk factors. The Center will host a public health roundtable to identify and prioritize public health actions to address social determinants of health related to dementia, and will develop tools and resources to support public health strategies for addressing social determinants of health.
- Current efforts include working with researchers at Wake Forest University to synthesize evidence about social determinants of health related to dementia risk factors and social determinants of health that present barriers to addressing dementia risk factors. The Center will conduct a workshop on social determinants of health at the Alzheimer’s Association International Conference on July 29, 2022.
- The Center will host a Dementia Risk Reduction Summit in 2023 to increase understanding and promote translation of science into public health action. The Center plans to convene Regional Learning Collaboratives for public health officials to increase understanding and develop workplans, expand partnerships with organizations that address risk factors, develop tools to support public health agencies in addressing risk factors, create a Project ECHO series to teach public health workers about dementia risk reduction, and develop and test risk reduction messaging.

“Addressing and Taking Action on Risk Factors--An AAA Response”

Victoria Jump, Director, Ventura County Agency on Aging

- The Ventura County Agency on Aging offers several programs and services that coordinate to identify people with or at risk for ADRD and connect them with comprehensive, culturally responsive care. The agency serves people with ADRD who live alone, those who live with a caregiver or partner, and those with intellectual or developmental disabilities. Services include respite, transportation, personal care, home modifications, caregiver support and training, and others. The Agency collaborates with a network of partners that support progress toward its goals. Service providers are trained to assess whether clients should be referred to additional services. Social workers reach out to clients who screen positive for depression and refer them to treatment. Staff are diverse and receive continuous training as well as annual training on serving people with intellectual or developmental disabilities. Ms. Jump encouraged meeting participants who are working to address risk factors to consider a partnership with their local Agency on Aging.

“Mind Your Risks (NINDS)”

Richard Benson, MD, PhD, Director, Office of Global Health and Health Disparities, NINDS

- Two-thirds of Americans have at least one potential risk factor for ADRD. Reducing risk factor prevalence by 15% per decade could reduce the number of people with Alzheimer’s disease by as much as 1.2 million by 2050. The Mind Your Risk Campaign focuses on Black men aged 28-45 years, who are the group at highest risk for developing hypertension. Focus group participants said materials were relatable and compelling and helped them to connect uncontrolled hypertension to dementia later in life. Participants believed campaign materials would inspire behavior change. NINDS is working with partners to disseminate the campaign message to the priority audience.

Discussion

- Dr. Bateman pointed out that it is difficult for people to meet behavioral health goals and difficult for interventions to facilitate efforts to achieve these goals. Dr. Benson said the public health community must prioritize lower prevalence of hypertension. Dr. Kim said it would be helpful for payers to reimburse the evidence-based practice of at-home blood pressure monitoring combined with professional counseling on hypertension prevention and treatment. Ms. Jump added that community service organizations can be an important partner in public health interventions. Dr. Sherry said it is important to engage underserved communities and to address structural determinants of health.

Panel Discussion: Lessons Learned from Public Health Campaigns

“Preventing 1 Million Heart Attacks and Strokes by 2027”

Judy Hannan, RN, MPH, Senior Advisor, Division for Heart Disease and Stroke Prevention, CDC

- The Million Hearts Initiative aims to prevent at least 1 million heart attacks and strokes over the next 5 years by promoting evidence-based strategies for cardiovascular disease prevention; convening public health care and public health champions; facilitating meaningful collaboration and resource sharing; and addressing health equity through specific policies, processes, and practices. Initiative priorities are to build healthy communities, optimize health care, and focus on health equity. The initiative applies a collective impact framework, which includes a common agenda that engages people; shared measurement; mutually reinforcing activities; continuous, consistent, and open communication; and a backbone organization.

“Youth Obesity Interventions”

Leslie Meehan, Director, Office of Primary Prevention, Tennessee Department of Health

- Community environments, including built environments, influence individuals' health and health choices. Greenways and green spaces support physical and mental health as well as community economies. It is important for multiple sectors to collaborate to support community health. Focusing on livability, quality of life, and supporting people in reaching their potential appeals to people with diverse political perspectives. Appealing to community sense of identity has been more effective than emphasizing public health. Training clinicians to understand how other community sectors' decisions affect public health and how clinicians can provide input on those decisions is an effective mechanism for public health improvement.

“Lessons Learned from Hypertension Program in Kaiser Permanente Northern California”

Mai Nguyen-Huynh, MD, MAS, FAHA, Chief of Neurology, Diablo Service Area, TPMG Regional Medical Director-Primary Stroke, Research Scientist II, Division of Research

- Kaiser Permanente's hypertension program components include no-cost, walk-in blood pressure visits with specially trained medical assistants, who forward results to a pharmacist or primary care physician. Quality performance metrics measure processes and outcomes at the clinic and clinician level and inform continuous quality improvement efforts. At baseline, less than half of patients effectively controlled their blood pressure. Currently, more than 80% do so.

Public Comments

- **Reverend Doctor Alexander Gee**, Co-founder, Black Leaders for Brain Health Community Advisory Board stressed the importance of including Black participants in clinical trials of ADRD treatments. The Revitalization Act of 1993 requires including minorities in these studies. As caretaker of a mother with dementia, he is concerned that available treatments may not work for her or her family. He called on the Council and funding organizations to withhold funding from research that does not include samples that support generalizability to racial/ethnic minority populations.
- Dr. Lamont read comments submitted by **Sue Cho**, primary caregiver for her mother, who was diagnosed with Alzheimer's disease at age 56. Ms. Cho pointed out that race/ethnic minorities are disproportionately affected by the disease and face cultural and linguistic barriers to diagnosis and care. She recommended updating the National Plan with a goal to train clinicians in cross-cultural assessment for dementia, access to Medicare services for patients with younger onset ADRD, eliminating the 2-year waiting period for benefits for people younger than 65 years who qualify for Social Security Disability Insurance benefits, and expanding Medicare coverage for ADRD medications.
- **Rachel Katz**, Manager of Federal Government Relations, National Down Syndrome Society, reminded the Council that, during its previous two meetings, representatives of the National Down Syndrome Society had recommended for the Council to form a subcommittee focused on improving diagnostic and clinical supports for people with intellectual or developmental disabilities. She reiterated this recommendation and noted that people with Down syndrome have elevated risk for Alzheimer's disease because they have three, rather than the typical two, copies of the chromosome on which the amyloid protein precursor of Alzheimer's disease is found.
- **William Mobley**, neurologist, Associate Dean for Neuroscience Initiatives, University of California, San Diego School of Medicine; Director, Down Syndrome Center for Research and Treatment; Chair, National Down Syndrome Society clinical advisory board, applauded CMS for removing restrictions on people with Down syndrome participating in clinical trials of monoclonal antibodies for treatment of Alzheimer's disease. He recommended ensuring people with Down syndrome have the same access to treatment and clinical trial participation as the general population.
- **Maria Kent Beers**, whose mother was diagnosed with frontotemporal degeneration in 2016 and died in 2020 at age 56, co-produces a podcast, "Remember Me," to tell stories about living with frontotemporal degeneration. Many families have shared stories about challenges in efforts to get an accurate diagnosis. She called for training health care providers to recognize the symptoms of frontotemporal degeneration and other types of dementia.

- **Wanda Smith** said several members of her family have a neurogenerative dementia caused by under-production of the protein progranulin. It is often referred to as an “other” dementia, which she finds demeaning. Ms. Smith said that clinical language used in discussing dementia is often confusing. She encouraged the Council to facilitate clearer communication about neurogenerative diseases and to focus on all types of dementia.
- **Matthew Sharp**, Advocacy Manager, Association for Frontotemporal Degeneration, said a diagnostic blood test is needed for frontotemporal degeneration, which is often misdiagnosed as a psychiatric disorder or undiagnosed, and treated inappropriately or not at all.
- **Maureen Japha**, Eli Lilly and Co., said CMS restrictions on aducanumab coverage undermine the intent of the accelerated approval pathway and the goals of NAPA and the National Plan. CMS has not described the circumstances under which the drug will be available outside of clinical trials. Eli Lilly encouraged the Council to urge CMS to expand coverage for drugs with positive confirmatory data.

Concluding Remarks

Dr. Carlsson noted that the Council’s next meeting will focus on recommendations for the National Plan and will be held on July 25, 2022.

The meeting adjourned at 4:00 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>.