

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

Washington, DC

July 29, 2019

WELCOME AND CHARGE FOR MEETING

Laura Gitlin, Ph.D., Chair

Dr. Gitlin opened the meeting at 9:04 a.m. and asked Advisory Council members to introduce themselves. She then discussed the agenda.

APPROACHES TO ALZHEIMER'S AND RELATED DEMENTIAS THERAPEUTICS

Allan Levey, M.D., Emory University

Dr. Levey began with Alois Alzheimer's 1906 discovery and illustration of senile plaques in the brain and neurofibrillary tangles--the two major pathologies for Alzheimer's disease which have been the subject of much research. Now we know the tangles are made up of the protein tau and the plaques are made up of amyloid, and that genetic mutations in tau or amyloid can cause forms of dementia.

Recently, investigators have been testing whether removing the tangles or plaques can alter or modify the disease. Tau studies are still in the early stages; there have been a lot of efforts around amyloid-based therapies but results have been disappointing. Nevertheless, insights have come from these failures.

We have also learned that timing of treatment is very important. In the past, treatment started in the mild to moderate stages of the disease, after people were symptomatic for 10-15 years. We now know that treatment is more likely to be effective earlier in the disease (individuals are still asymptomatic, but pathologies are present) or as preventative treatment (individuals are still cognitively normal, and pathologies are not present). A series of amyloid-based therapies are still being tested, and we have reason to be optimistic.

Importantly, these tangles and plaques are not restricted to Alzheimer's disease, but have also been found in Down syndrome, which has been shown to result from the over-production of amyloid.

Amyloid plaques are the first pathology of the disease that appears, followed by neurofibrillary tangles. These two pathologies now can be used as biomarkers to identify people in the pre-clinical (asymptomatic) stages of the disease. Clinical evaluations are typically done because of the syndrome/symptoms but biomarkers can

now be measured to confirm that it is Alzheimer's disease. Further complicating the matter, most people have a mixture of pathologies, not just Alzheimer's disease. Researchers want to develop biomarkers for all the other co-existing pathologies (e.g., pathologies of Lewy Body dementia) and develop therapeutic approaches based on these biomarkers.

Richard Hodes, M.D., National Institute on Aging (NIA)

Over the last few years, genetic findings in Alzheimer's and other dementias have accelerated incredibly. One initiative, the Accelerating Medicines Partnership (AMP), is a consortium of six academic teams that work together with foundations and pharmaceutical and biotech organizations; over the past 4 years, AMP has established a centralized data resource, developed a variety of experimental validation models, initiated novel biomarker discoveries, and nominated more than 100 candidate targets, which are undergoing data-driven prioritization for further preclinical validation.

Geroscience posits that changes that occur in aging may be accelerated in disease states. One focus has been on senescent cells, cells which no longer divide and grow but have an active phenotype: they secrete a large number of biologically active factors that affect the function of neighboring, non-senescent cells. They accumulate in all of us and express certain genes to excess (e.g., *p16*).

These senescent cells can be selectively eliminated through genetic manipulation or drug treatment. For example, treating senescent cells with senolytics (drugs that reverse resistance to cell death) has been found to extend the lifespan of older mice and improve function. Important for Alzheimer's disease, clearance of senescent glial cells has been shown to prevent tau-dependent pathology and improve cognition in mice.

The NIA is funding several clinical trials which target different pathways thought to underlie Alzheimer's disease. From industry, numerous Alzheimer's disease drugs are in the development pipeline as of 2019. Most (61%) are disease-modifying therapies, followed by neuropsychiatric symptoms (28%) and symptomatic cognitive enhancers (11%). NIA has some 200 intervention and prevention trials underway related to Alzheimer's disease and related dementias (AD/ADRD), including 61 care and caregiver interventions.

Bradley Hyman, M.D., Massachusetts Alzheimer's Disease Research Center

The NIA is currently funding clinical trials to test whether lifestyle interventions can mitigate the impact of Alzheimer's disease. For example:

- Exercise in Adults with Mild Memory Problems is testing the effects of physical exercise on cognition, functional status, brain atrophy, and blood flow, and assess cerebrospinal fluid biomarkers of Alzheimer's disease in age 65-89 adults with mild cognitive impairment (MCI). This is scheduled for completion in 2022.
- The MIND Diet (Mediterranean-DASH Intervention for Neurodegenerative Delay) is testing cognitive decline and brain neurodegeneration among those 65 and older

without cognitive impairment who are overweight and have suboptimal diets. It is also scheduled for completion in 2022.

- Processing Speed Training to Preserve Driving and Functional Competencies in Mild Cognitive Impairment tests the capacity of an enriched version of processing speed training to preserve functional abilities in a clinical population with quantified genetic and neuroimaging and co-morbid cardiovascular disease (CVD) biomarkers.
- The FINGER trial is a long-term clinical trial suggesting that a multi-domain intervention with exercise, diet, cognitive and social stimulation, and management of vascular and metabolic risk factors may benefit cognition in subjects at risk of dementia. The U.S. POINTER study was initiated to test the generalizability of the results of the FINGER study.
- SPRINT-Memory and Cognition in Decreased Hypertension (SPRINT-MIND) is a trial that targeted systolic blood pressure in an effort to determine whether intensive blood pressure control can reduce the occurrence of dementia. Participants assigned to the intensive treatment experienced reduced rate of developing MCI and reduced rate of composite MCI and probably dementia as compared to the Standard treatment group.

Over the next 10 years, we expect to see continued improvements in neuroimaging for Alzheimer's disease-related molecular changes, further understanding from genetics and other -omics research, new drug trials and personalized medicine approaches, and exploration of diversity across all facets of disease research.

Gene therapy approaches have shown promise in treating devastating human diseases. Two examples of novel gene therapy is one to treat Leber's congenital amaurosis (the therapy prevents blindness in these children) and another to treat infantile spinal muscular atrophy (enabling these children to walk).

New approaches are already leading to optimism despite disappointments in anti-amyloid therapeutics. We have already achieved earlier diagnosis and earlier interventions. Future therapeutic approaches, possibly in the next few years, could include gene therapy, brain neuromodulation, nonpharmacological interventions, new targets from genetic studies, new targets from AMP, and new approaches to improve clinical trial design and hasten results.

Comments & Questions

- *Laura Gitlin* reframed the current situation, saying failures still teach a lot. The field is complicated and funding drives research. Meanwhile outcomes and therapy are bound to timing, so early-stage monitoring is important. *Dr. Hyman*: Diet and exercise are also important. NIA has assumed the role of accelerating work on biomarkers by funding an additional trial for biomarkers. *Dr. Hodes*: A few years ago, people were treated who were thought to be in early stages, but we need to know that we are targeting the right process in the right people and engaging the right target. Enormously important lessons have been learned from these trials.

- In response to *Deborah Olster*, *Dr. Hodes* said, it is important to be able to mimic what a gene does. *Dr. Levey* added that a gene involves what makes people resilient.
- *Gary Epstein-Lebow*, said his father has had colon cancer for several years. First, they needed a navigator to negotiate the health care system. The treatment he received exhibits how and how fast the field is moving. *Dr. Hyman* agreed that much revolves around the patient and caregivers. It is important for personnel at a clinic to be aware of the options and be able to relate them accurately to the client. We are defining who in the health professions will should have that needed expertise. *Dr. Hodes* added that the use of technology is increasing, particularly of apps in progressive care. *Joan Weiss*: All this shows the importance of having a health navigator immediately. Concomitantly, we may be able to gather a more diverse population.
- *Shari Ling*: This discussion leads to thinking about a future state that includes specialties. We also have to think about the entire system and how it works. An immediate opportunity appears with budget control having been a key focus for primary care. There is evidence that we should think about blood pressure, for example, for subpopulations. That could be a component, but what does the change package look like? *Dr. Levey*: The SPRINT-MIND trial shows the potential of these collaborations. If we are ready to have value-based care, we need a value-based approach to blood pressure. By using apps, a patient does not have to come to an office once a year but can check it at home.
- *Laura Gitlin*: We also need partnerships.
- *Shari Ling*: We have had projects on dementia care and we need more.
- *Cynthia Huling Hummel* noted that often, as was her experience, the patient leaves her doctor's office with a diagnosis, but no practical ways to deal with it.

CHOOSING INDICATORS

Helen Lamont, Ph.D. and Emma Nye, Office of the Assistant Secretary for Planning and Evaluation (ASPE), Department of Health and Human Services (HHS)

Ms. Nye showed graphs of progress on key indicators related to dementia work since 2011, recognizing that we want to measure progress and look at a broader range of indicators. The Driver Diagram was used to map indicators to the National Plan--some to multiple actions, some to the strategy level. Not every action can be measured quantitatively; some are more qualitative. Not all indicators were available since 2011, but there is general recognition of the importance of measuring progress. Many indicators align with multiple action steps in the National Plan.

Thought is being given to changing the National Plan because some categories had not been defined in 2011. Therefore, some metrics are not cumulative, but annual, although they are striving for cumulative metrics. The number of research projects aimed at treating or preventing AD/ADRD increased by as much as three times compared with the number in 2016 at the HHS National Institutes of Health (NIH), U.S. Department of

Veterans Affairs (VA), National Science Foundation, HHS Human Resources and Services Administration (HRSA), HHS Centers for Disease Control and Prevention (CDC), and HHS Administration for Community Living (ACL).

Comments & Questions

- *Laura Gitlin* asked what federal agencies do with these numbers. *Dr. Hodes*: The use of cumulative data confuses matters. When soliciting numbers we need to be consistent. *Dr. Lamont*: Part of the challenge is figuring out what the goal should be because some measures will not increase at such a rapid pace without leveling off. Many measures are also limited by the availability of funding.
- *Cynthia Huling Hummel* acknowledged the PowerPoint on caregivers who received dementia education, but asked whether there were measures on the number of people with dementia who receive dementia education. *Dr. Weiss* responded that HRSA does not collect data on patients, although they could in the future. It is somewhat of a challenge to get certain data elements because of how grantees collect data. *Katie Brandt* reported that her clinic provides training for patients.
- *Laura Gitlin*: Some indicators are missing, and we have to make sure measurements align with what an agency's goals are. The goal of data tracking needs more attention. *Dr. Olster* asked for clarification as to how data were collected. *Dr. Lamont* said the agencies submitted the indicators they thought were most meaningful for their work on dementia.
- *Debra Cherry*, thought this was a good beginning. Another goal is to increase coordination among federal agencies. Is there a way to show whether agencies are coordinating with one another efficiently/effectively leverage the resources Congress allots. *Dr. Lamont* has been considering whether and how to show these measures of progress in the National Plan. She asked for input as to particular topics that should be included in measures of progress, for example, how well we serve minority communities or people with dementia.
- *Angela Taylor* observed that the graphs presented show that a lot of work has been done by agencies involved. As we move forward, she would like to see whether we can get data from agencies such as the HHS Food and Drug Administration. She would like to know the progress made in changes in Investigational New Drug submissions, for example.
- *Bruce Finke*: This is very early work, but from a plan perspective, a lot of data show where we are going. Unfortunately, some work has been done with no systematic way to evaluate accomplishments. For example, it is hard to find the data for the Indian Health Service (IHS). A lot of available data are not useful, and the data we want we cannot get. We need to know what data is both available and useful. Data tracking and synthesizing can indicate what measures are missing and what goals are not being tracked adequately. One thing missing is outcome data, especially around care and services. For example, we can show training of caregivers, but not competence of caregivers. This work should point out measurement plans. But measurement is expensive, and we have not invested in measurement. Investing in measurement would be an improvement.
- *Laura Gitlin* asked what the immediate next step is. *Dr. Lamont* suggested forming a subcommittee to define key indicators, then maybe focusing on a few important

things that the Federal Government is not doing. We need to think about what story we want to tell and what data we need to tell that story.

- *Joan Weiss*: These data are numbers of things (e.g., Geriatrics Education and Training). A number of caregivers were trained, but not with our grant funds. With Geriatrics Workforce Enhancement Program (GWEP), we trained across the educational continuum. These data were put in the Office of Management and Budget package. But these are only numbers; they do not show impact. Applications for continuing funding go beyond numbers to show impact, which has to be shown incrementally. It is hard to adapt some areas (e.g., primary care).
- *Laura Gitlin*: This is a critical discussion and it is important to understand the process. The discussion shows where we want to go with the Driver Diagram.

STARTING CONVERSATIONS ABOUT DEMENTIA IN INDIAN COUNTRY: A PUBLIC HEALTH ROAD MAP

Public health bridges the gap between biomedical research and community services, and it has a role to play in Alzheimer's disease and brain health. Public health tries to minimize risk, whereas clinical care focuses on treating the present. The Healthy Brain Initiative (HBI) Road Map for Indian Country is starting conversations about dementia in Indian Country.

Dementia in Indian Country

Blythe S. Winchester, M.D., M.P.H., C.M.D., Cherokee Indian Hospital
[via telephone]

The American Indian/Alaska Native (AI/AN) elder population is growing and exhibits the highest prevalence of CVD and high rates of disability in general. This is complicated by cultural considerations including language (a huge consideration), historical experience, use of traditional Indian medicine, and framing and context for understanding illness.

Likewise, caregiving must be framed with these cultural considerations. For example, among AI/ANs many more caregivers are involved, the culture is matriarchal, the social situation at home may be complex, and abuse may be a factor. The caregiver must deal with whether the "little people" or "boogers" are hallucinations or cultural practices. Caregivers must also combat the idea that dementia is just normal aging.

Then the client has the added disadvantages of the lack of continuity caused by staff turnover and unfamiliar relationships in some clinics. Patients can go to Council members to seek additional assistance for dementia care. They need to know what is available and how to access it.

Developing the New Road Map for Indian Country

Molly French, M.S., Alzheimer's Association

Concern about dementia is increasing in Indian communities. The Alzheimer's Association is working in collaboration with CDC, but public health practitioners and solutions for Indian Country, in general, must come from within the community using strength-based strategies. HBI Road Map for Indian Country is tailored for leaders of AI/AN communities to help public health leaders begin these necessary conversations. It offers public health strategies to promote brain health, address dementia, and help support caregivers. The Leadership Committee decided to create a Tribal Road Map for Indian Country because the HBI Road Map for State and Local Public Health did not speak to Indian Country. Input was gathered from regional Tribal health boards and members, Tribal health leaders, Tribal aging service leaders, Tribal government officials, and many other experts.

The Road Map for Indian Country is intended to be a conversation starter that will prompt local planning and encourage public health strategies for the good of all. Strategies to achieve this include educating and empowering community members, collecting and using data, and strengthening the workforce. The Road Map for Indian Country can be found at <https://alz.org/professionals/public-health/road-map/tribal-roadmap> or <https://www.cdc.gov/aging/index.html>.

Tribal Health Leaders and AD/ADRD

Carolyn Angus-Hornbuckle, J.D., Mohawk Tribe, National Indian Health Board (NIHB)

NIHB was formed because Tribal leaders wanted an organization dedicated to Indian health that represents all 573 federally-recognized Tribes (which are each unique) to give Congress and courts a single voice.

To obtain data on incidence dementia, Kaiser Permanente Northern California (KPNC) enrolled Tribal members who were 60 years of age as of January 1, 1996, and had no symptoms of dementia. Dementia incidence rates among AI/ANs are second only to those of African Americans. A study of prevalence of dementia in the First Nations population of Alberta (1998-2009) indicated that physician-treated dementia was disproportionately prevalent among those who were younger and male.

The IHS response to AD/ADRD is not comprehensive. The focus of IHS is: awareness in the community, workforce competency in recognition, diagnosis, and management; system competence to meet the needs of individuals with dementia; reduction of risk factors for dementia; measurement to guide improvement in care and services; and availability of long-term services and supports (LTSS).

Feedback from Tribal community leaders on the Road Map for Indian Country has been positive. We listen to partners and Tribal leaders to ensure that we capitalize on

community strengths. Our elders are the protectors of our culture and they are honored members of the community.

Indian Health Service

Bruce Finke, M.D., Indian Health Service (IHS)

Only a few years ago, GWEP was presented to this group. Dr. Winchester's report was a follow-up to that. A few studies have given insight, such as KPNC's study of a large mature population, and the study from Alberta indicating a younger and more male population.

Population-based risk factors are a big problem. They are (in order of prevalence) diabetes, unintentional injury, nephritis and nephrotic syndrome, chronic liver disease and cirrhosis, CVD and stroke, hypertensive disease, and Alzheimer's disease. When addressing Alzheimer's disease, IHS makes up the smaller part. The majority of health care entities are Indian owned and operated. This complex environment includes other Tribal organizations and universities, which offer a number of ways to address the situation.

Increasing awareness in the community will drive change. Two significant issues are caregiver support and the notion of care system navigation. Risk factors point out the issues (e.g., good diabetes control). CDC is helping to build tools that create changes. But first we need to know what measures in Indian health will advance dementia care.

Healthy Brain Initiative

Lisa McGuire, Ph.D., Centers for Disease Control and Prevention (CDC)

CDC's focus is on educating and empowering community members about brain health and talking to a doctor about their memory concerns, collecting and using data, and strengthening the workforce. Important issues are recognizing warning signs of AD/ABD and knowing how to start a conversation both within the community and with providers.

CDC developed several resources to provide community members with information about dementia and caregiving. The Behavioral Risk Factor Surveillance System (BRFSS), a national state-based surveillance system, collected data on subjective cognitive decline (SCD; 49 states, DC and Puerto Rico) and caregiving (44 states, DC and Puerto Rico). These data are actionable were used to develop infographics, specific to AI/ANs, for SCD and Caregiving. CDC in collaboration with Association of State and Territorial Health Officials, created a series of communication materials emphasizing the connection between heart and brain health. These materials include posters, flyers for clinics and health fairs, radio public service announcements, micro-videos for clinics, a provider guide, and newspaper articles for the Indian Country Today Media Network.

CDC, in collaboration with the American College of Preventive Medicine, has developed a free continuing education course--Brain Health. It explains brain health terminology,

defines and describes risk factors, and summarizes lifestyle medicine and management strategies. They have also collected resources on brain health for physicians and patients. Additional CDC public health programs and resources for Indian Country include Good Health and Wellness in Indian Country; Tribal Epidemiology Centers; Tribal Practices for Wellness in Indian Country; and Healthy Heart, Healthy Brain Messaging.

The next steps are for CDC to continue to support states, territories, and Tribes with data for action and with support to implement new Road Map for Indian Country. This includes integrating the brain health messaging into chronic disease messaging and establishing action institutes to stimulate strategic changes in policy, systems, and environments supporting Road Map implementation. Dr. McGuire encouraged everyone to stay connected to CDC and sign up to receive their materials at <https://www.cdc.gov/aging/index.html>.

Comments & Questions

- Replying to *Dr. Epstein-Lebow*, *Dr. McGuire* said the available public service announcements are very short, approximately 30 seconds or so.
- *Shari Ling* said that these presentations illustrate a lot of work, particularly on risk factors such as kidney disease and diabetes. She wanted to know about lessons learned and what can be transferred. *Dr. Gitlin* observed that disease manifests differently in different cultures. Just collecting data on these differences will go a long way.

FEDERAL UPDATES

Annual Bypass Budget

Richard Hodes, M.D., National Institute on Aging (NIA)

The NIH annual bypass budget is presented at this time of year; this year, the FY21 bypass budget was released. This budget was developed based on NIA research implementation milestones, which are derived from internal and external input to ensure comprehensive inclusion of priorities. Until 2025, Congress has mandated that NIH submit estimates of resources each year needed to accomplish, at maximum efficiency and speed, the goals of the National Plan. The cost of additional resources needed for new AD/ADRD research FY21 has been estimated at \$353 million.

The AD/ADRD research implementation milestones database (<https://www.nia.nih.gov/research/milestones>) is updated annually to enable this determination. Resources are available online, including considerations for future budgets. The International Alzheimer's and Related Dementias Research Portfolio (IADRP) is a database that brings together funded research supported by public and private organizations in the United States and abroad.

The Dementia Care and Services Summit will be held March 24-25, 2020, in the Natcher Building on the NIH campus.

Comments & Questions

- *Laura Gitlin* asked how distribution of funds is decided. *Dr. Hodes* replied that they took all recommendations and reported what would be needed to accomplish them.
- *Allan Levey* asked how funding gaps are translated. *Dr. Hodes* said milestones are estimates 2 years before the budget occurs. However, investigator-initiated research does not necessarily correspond to these categories. There is also a level of increase created by solicitations to the public and other mechanisms that have supported research. By 2021, we will be dealing with milestones beyond those we have considered. This is a professional judgment separate from the appropriations process.

NAPA Clinical Subcommittee Federal Updates

Shari Ling, M.D., Centers for Medicare & Medicaid Services (CMS)

CMS has initiated several efforts to improve service, including the following:

- In April, CMS announced Primary Care First Model Options, a voluntary 5-year payment option that rewards value and quality by offering an innovative payment structure to support delivery of advanced primary care. The model is based on prioritizing the doctor/patient relationship, enhancing care for beneficiaries with complex chronic needs and high-need seriously ill patients, reducing administrative burden, and focusing financial rewards on improved health outcomes.
- In June, CMS issued a request for information on reducing administrative burden in an effort to “put patients over paperwork.” CMS is looking for the factors that make care effective and thinking about how to streamline requirements.
- In June, CMS finalized a rule to update and modernize requirements for Programs for All-Inclusive Care for the Elderly.
- In July, CMS released a Notice of Proposed Rulemaking and a Final Regulation to help assure safety and quality in nursing homes.
- On July 10, CMS implemented the Medicaid Innovation Accelerator Program webinar to introduce several new measures created for voluntary use for state Medicaid programs.
- Independence at Home is in its fourth year and has saved Medicare approximately \$33 million (about \$384 per enrolled beneficiary per month), attesting to the value of home-based primary care.
- The Improving Medicare Post-Acute Care Transformation Act requires standardized, interoperable data in most Medicare settings, which facilitates care coordination. The update requires interoperable data for post-acute care.
- The Medicare Part D Prescriber Public Use Files provide information on the specific pharmaceuticals prescribed by individual providers and paid for under Part D. A 30% reduction in use of antipsychotics has been observed. At the same time, CMS recognizes that there are appropriate uses for antipsychotics and relies on the clinical team to distinguish the needs and uses.

- Two publications--"Physical and Mental Health Integrated Care Needs," and "Adult Beneficiaries with Complex Care Needs"--exemplify Medicaid's new measures of quality.
- The updated chartbook for co-morbidity in chronic conditions, including AD/ADRD, creates a business case for why clinical trials matter. Most people have more than one morbidity and dementia complicates care of any other condition.

Long-Term Services and Supports Subcommittee (LTSS)

Helen Lamont, ASPE

New ASPE reports on long-term care include:

- Analysis of Pathways to Dual Eligible Status (<https://aspe.hhs.gov/basic-report/analysis-pathways-dual-eligible-status-final-report>)
- Loss of Medicare-Medicaid Dual-Eligible Status: Frequency, Contributing Factors and Implications (<https://aspe.hhs.gov/basic-report/loss-medicare-medicicaid-dual-eligible-status-frequency-contributing-factors-and-implications>)
- How Many Older Adults Can Afford To Purchase Home Care? (<https://aspe.hhs.gov/basic-report/how-many-older-adults-can-afford-purchase-home-care>)
- What Is the Lifetime Risk of Needing and Receiving Long-Term Services and Supports? (<https://aspe.hhs.gov/basic-report/what-lifetime-risk-needing-and-receiving-long-term-services-and-supports>)
- Assessing the Out-of-Pocket Affordability of Long-Term Services and Supports? (<https://aspe.hhs.gov/basic-report/assessing-out-pocket-affordability-long-term-services-and-supports-research-brief>)
- Support and Services at Home (SASH) Evaluation: Evaluation Findings, 2010-2016 (<https://aspe.hhs.gov/basic-report/support-and-services-home-sash-evaluation-sash-evaluation-findings-2010-2016>)

Administration for Community Living (ACL)

- ACL reported that in June, the Alzheimer's Disease Programs Initiative (ADPI) had awarded grants totaling more than \$6 million to States and communities. ADPI grant applications are due August 13, 2019 (total funding is \$10.7 million).
- The National Alzheimer's and Dementia Resource Center hosted webinars (ACL dementia grantee-developed products) on social isolation and loneliness among people living with dementia (PLWD); caregiving, engaging, training, and implementing programs that use volunteers; and stigma toward PLWD.
- New webinars are: Financial Capacity for People Living with Alzheimer's and Their Caregivers on August 6 at 2p.m. EST, and Strategies for Sustaining ACL Dementia Grant Projects on September 17 at 1p.m.
- Two webinars were designed to ensure that professionals are knowledgeable about the impact of Alzheimer's disease and brain health on families, and understanding critical community supports and resources (April and May 2019).
- In response to requests, the National Alzheimer's and Dementia Resource Center will soon be available (<https://nadrc.acl.gov/>). It will contain practical strategies, highlights of grantee-developed resources, dementia-capable States and

communities, and grantee-implemented evidence-based and informed interventions (e.g., Vermont's long-term care services program, which can be used as a model).

- The National Institute on Disability, Independent Living, and Rehabilitation Research has a new funding cycle (FY19-FY24) underway. This offers another opportunity to look at psychology as it relates to dementia.
- The Administration on Aging awarded logistics contracts for the Reforming American Immigration for Strong Employment Act and for the Grandparents Raising Grandchildren Act.

Lisa McGuire, CDC

- CDC update their public data portal on Alzheimer's disease and healthy aging. Information posted includes results from the 2017 BRFSS data on variable related to overall health, cognition, and caregiving.
- They also are finalizing the Spanish translation of their infographics on Subjective Cognitive Decline and on Caregiving.
- Released the third data brief in the series of five on CVD and risk factors.
- A new podcast series is entitled Aging and Health Matters was launched.
- Two recent CDC web features and "Did You Know" were released in May and June. These focus on the truth about dementia and aging and disparities in dementia.

PUBLIC COMMENTS

Diana Blackwelder, Advocate

Ms. Blackwelder has been unable to get a response from the Amazon.com website, which shows disturbing images of people being forcibly restrained. These images will give caregivers (who may not be well educated) the idea that such restraint is appropriate care for people with dementia. Generally, people do not get credit for providing support for PLWD.

Carla Danesi, Caregiver

Ms. Danesi has been her mother's caregiver since her illness began, and she chose to keep her mother at home. The illness has caused suffering, but this Council can make a change (e.g., having to wait 5-10 years for a new treatment is unacceptable).

Mary Hogan, Family Advocate

Ms. Hogan distributed a pamphlet on dementia among people with intellectual disabilities with photos produced by organizations including the Alzheimer's Association, which has been translated into Spanish. The cover shows Irma who was born in 1945, lived a rich life, and had a long decline, but did a lot in those 8 years. For many others that decline is a real struggle.

Maryanne Sterling, Caregiver

Of Ms. Sterling's and her husband's four parents, three lived with dementia. When the last of the three parents died, it was the first time in her adult life that Ms. Sterling did not have a parent with dementia to care for. She saw that end-of-life care was given by people who had no idea how to do it and who were unable to find resources. Women are disproportionately affected when their family members become disabled and the duration of these conditions is seldom discussed. Meanwhile, Medicaid eligibility is painfully complicated, so people drain their own resources. Another problem is that the research community remains slow to adopt change, so the afflicted need to deal directly with researchers. Often sufferers and their caregivers cannot leave their homes to get whatever therapy may help.

Charles Alcorn [read by Dr. Lamont]

Alzheimer's disease research funding at NIH has increased to allow development of new techniques, yet Alzheimer's disease research and productivity may be in decline. The number of disease-modifying drugs declined 14% in 2018 and 11% in 2017, funded by both private and public investment. The Advisory Council should evaluate performance.

PRESENTATION, DISCUSSION, AND VOTING ON RECOMMENDATIONS

The subcommittees reviewed all recommendations to determine whether they are still needed or should be removed or revised.

Research Subcommittee

Angela Taylor, Lewy Body Dementia Association

The subcommittee's nine themes are:

1. Robust biomedical and holistic strategy.
2. Sufficient resources.
3. Silos minimized.
4. Optimal infrastructure and research climate.
5. An inclusive role for the dementia community.
6. Global leadership role.
7. Broad dissemination.
8. Commitment to quality.
9. Continuous and objective process improvements.

Recommendation 1. The 2018 National Plan should continue to provide a robust, comprehensive, collaborative, and transformative scientific road map for achieving the goal of preventing, effectively treating, and providing effective care and services for AD/ADRD by 2025.

The only change was to add under Section A: “Federal agencies should support global efforts to address issues of research, care and services, and workforce development in order to facilitate international collaboration and minimize silos of knowledge.”

Recommendation 2. A top priority remains the urgent need for Congress to continue to increase annual federal research funding sufficient to meet all the 2025 goals, across biomedical, clinical, LTSS, and public health.

Recommendation 3. Emphasis should be given to the standardization of terminology across the spectrum of cognition in neurocognitive disorders by all agencies involved in the National Plan, to reduce ambiguity over confusing or overlapping terms, reduce stigma associated with AD/ADRD, and improve public awareness of AD/ADRD and access to relevant resources and services.

Comments & Questions

- *Laura Gitlin* thought it critical to link the discussion of nomenclature back to the science. *Ms. Taylor* agreed. As science evolves, so must the nomenclature. Process recommendations following the summit stated that we make sure we have research groups focused on clinical care. Something to this effect can be added at the end.

Recommendation 4. A major area of emphasis by all federal agencies involved in the National Plan should be the enhancement of recruitment efforts for research involving those with, or at risk of developing, AD/ADRD.

Recommendation 5. Federal agencies should develop a strategy and infrastructure to increase ethical and open sharing of, access to, and utilization of research data, with a continued emphasis on ethics, in collaboration with academia, biotech, and information system industries. This strategy should accelerate the pace of scientific discovery in AD/ADRD science by addressing a comprehensive range of issues including cross-sector data sharing practices and policies, data harmonization and interoperability, and the training of data scientists in AD/ADRD research.

Comments & Questions

- *Laura Gitlin* asked what would be required to develop the infrastructure to enable this data-sharing. *Ms. Taylor* said the Alzheimer’s Disease Summit emphasized this. *Dr. Hodes* thought it was not at a point where funding is prohibitive. *Dr. Gitlin* emphasized the need for inclusion (e.g., of community agencies).

Recommendation 6. All federal and non-governmental agencies funding AD/ADRD research, along with the Patient-Centered Outcomes Research Institute, academia, and industry, should establish the engagement of the AD/ADRD community as a standard practice in both participating in setting national research priorities for AD/ADRD and throughout all stages of clinical research and care, and services and support research.

Recommendation 7. To expand access to brain tissue needed for AD/ADRD research purposes, NIH should explore gaps in tissue availability for research and review and refine the current infrastructure at the NIH NeuroBioBank and Alzheimer's Disease Research Centers (ADRCs) to fill these gaps. NIH should consider the value of widening outreach to accept brain donations from clinically well-characterized individuals, such as those receiving clinical care at dementia research sites like ADRCs and Udall Centers.

Comments & Questions

- *Angela Taylor.* This recommendation is new for 2019. *Dr. Lamont* added that the recommendation will be finalized by October.

Clinical Care Subcommittee

Gary Epstein-Lubow, M.D., Emory University

The subcommittee's six themes are:

1. Advancement of themes and results of the National Research Summit on Dementia Care.
2. Public education about early detection and diagnosis.
3. Workforce development.
4. Attention to best practices in AD/ADRD.
5. Encouragement of health system models that align performance, care quality, and payment.
6. Encouragement of additional use of metrics to assess progress of the National Plan.

First five recommendations are from last year. Recommendation 1 may be combined with 3 after this year.

Recommendation 1. Advance the themes and recommendations of the 2017 and 2020 National Research Summits on Care, Services, and Supports for persons with dementia and their caregivers.

Comments & Questions

- *Angela Taylor.* It is important to raise the person-centered care component to the top level. *Susan Cooley* fully supported this recommendation.
- *Helen Lamont* said the subcommittee had discussed whether this or a milestone document should remain in the records. They decided to keep them separate.

Recommendation 2. Educate the public about early detection and diagnosis of AD/ADRD, person-centered care planning, and the importance of and ways to enter into research.

This year, person-centered care planning at the highest level was added.

Comments & Questions

- *Joan Weiss*: Antipsychotics are being addressed in geriatric care. In the face of behavioral changes, workers should be trained on how to recruit individual researchers in addition to researchers working on clinical trials.

Recommendation 3. Enhance the current and future workforce through education to better address the needs of persons living with AD/ADRD and their caregivers.

Comments & Questions

- *Cynthia Huling Hummel* said she would add the need for this recommendation especially with younger onset (e.g., it took her 8 years to get a diagnosis).
- *Katie Brandt* noted that training offers the wonderful results of empowering people.

Recommendation 4. Determine a process for reaching consensus on definitions of best practices for comprehensive care of AD/ADRD at all disease stages.

Dr. Epstein-Lubow encourages the Council to find some process to identify best practices. The question now is what entity would be the location for that activity.

Comments & Questions

- *Shari Ling*: With best practices, a lot happens at the local level. Clinical entities are responsible for knowing the guidelines. The disadvantage is that practices are specialty specific. We need something more and broader, something like what the National Academy of Sciences (NAS) has, which also has an eye on the founding construct.
- *Arlene Bierman*: Our response to dementia now is mostly focused on addressing clinical interventions.
- *Bruce Finke*: This will be challenging under any circumstances. Maybe it should not be a single set of guidelines, but several that are each internally coherent-- maybe we should find a route and not a trail. Then see what we come up with and let the market select the particular route. *Dr. Bierman* thought we would find some models in particular settings. The Agency for Healthcare Research and Quality (AHRQ) is testing those as well as implementing them.
- *Laura Gitlin*: We should think about fidelity in terms of principle and not a specific procedure. We may have to reframe our recommendations.
- *Shari Ling*: It also depends on how fast you want to use it. One initiative already underway is NAS's Leadership Consortium, but this is also a matter of funding.

Recommendation 5. Encourage further development, evaluation, and use of health care models for AD/ADRD that align performance measures, the experience of care by persons living with AD/ADRD and their caregivers, and payment.

Comments & Questions

- *Shari Ling*: Models become more difficult when you think about trajectory. They should all drive toward a better outcome.

- *Arlene Bierman* noted that some models may be of use to others. Dr. Hodes suggested those used by NAS and NIA.

Recommendation 6. Encourage early use of metrics to assess progress of the National Plan to address AD/ADRD.

Comments & Questions

- *Debra Cherry*: This would apply for the personal care recommendation, which should be stated somewhere. *Dr. Lamont* would expect it to be included in the National Plan.
- *Angela Taylor* agreed on the need to develop metrics. *Dr. McGuire*: To develop useable metrics we need to know what the endpoint is and how these metrics will be used.
- *Shari Ling*: If we just use what we already have, it will not take us where we want to go.
- *Gary Epstein-Lebow* concluded that the recommendation will stay for this year with some wordsmithing.

Long-Term Services and Supports Subcommittee (LTSS)

Debra Cherry, Ph.D., Alzheimer's Greater Los Angeles

LTSS has three themes:

1. Improve access to LTSS, including home and community-based services (HCBS).
2. Improve integration of clinical care with HCBS including systematic identification, assessment, support, and engagement of family/friend caregivers by health care systems.
3. Provide high-quality, person and family-centered LTSS that address behavioral and psychiatric symptoms of AD/ADRD across care settings.

Recommendation 1. Improve access to affordable LTSS. By 2025, programs beyond Medicaid that provide LTSS (e.g., the Older Americans Act, and state and non-profit programs) should be expanded to support individuals and families with unmet needs, including underserved, diverse populations. Federal agencies and states should build workforce capacity to provide dementia-capable LTSS. Health care systems should expand access to HCBS.

Comments & Questions

- *Becky Kurtz*: We are challenged by not being able to serve people under age 50. *Ms. Brandt*: The State of Massachusetts had a meeting whose specific target was to support younger groups.

Recommendation 2. Improve integration of clinical care with HCBS. By 2025, 20% of hospitals and primary care practices serving people living with AD/ADRD will have specific procedures in place. CMS will have quality measures in place that will encourage health care systems (health plans) to implement these recommendations.

Comments & Questions

- *Laura Gitlin* asked how the subcommittee arrived at 20%. *Dr. Cherry* said she consulted the John A. Hartford Foundation, which runs an age-friendly health care system that follows a group that intends to reach 55% of the population.
- *Gary Epstein-Lebow* referred to effective approaches rather than best practices. He suggested that next year, the work here relates to this.
- In response to *Ellen Blackwell*, *Dr. Cherry* said there was no problem adding individuals and care plans, but there is a role beyond CMS whereby caregivers get a needs assessment. *Dr. Weiss*: The recommendation speaks to what the partnership does even though CMS provides caregiver training. We can work on metrics. *Dr. Gitlin*: This is aspirational, but we need it now. *Dr. Weiss*: We need to make sure the caregiver is part of the professional team.
- *Shari Ling*: All of this should be happening now. It is a little harder to know whether it is in fact happening. We have here a processing issue. What does it look like when clinical care is not integrated with HCBS? This should be tied to a measurable outcome. Are we asking for measurement of systems or measurement of the health of the client? *Dr. Cherry*: It is really hard to find single metrics that work for all long-term health care. This is an attempt to state the issue. It can be refined over time and we can add measurement over time. But if we do not state the issue here, no one knows it needs to happen. *Dr. Gitlin*: We all agree in principle, but we need some wordsmithing.

Recommendation 3. Individuals with AD/ADRD will not be prescribed antipsychotics unless clinically indicated. Research should be funded through federal agencies (NIA, AHRQ, National Institute of Nursing Research [NINR]) to delineate barriers to adoption of evidence-based interventions and to also identify bright spots where uptake is achieved. Federal agencies and other organizations should disseminate promising evidence supported interventions. Federal agencies (HRSA, ACL, CDC, VA, IHS, NINR) and other organizations should continue to build workforce capacity to deliver person-centered care as well as the use of promising and/or evidence-derived non-pharmacological interventions for behavioral and psychological symptoms of dementia. Federal agencies should create care or payment models for use of effective evidence-based interventions. Federal agencies should encourage measure development for HCBS, including measures that address challenging behavioral symptoms. By 2021, HHS should develop a coordinated process for measuring antipsychotic medication use that will delineate inappropriate use, which can be applied to community as well as facility residents and can be used to calculate prescribing trends over time. Data sources to be considered for this purpose could include Medicare Part D--prescriber-specific data, State Medicaid Drug Utilization data, Vendor Drug Programs data, and National Partnership Quarterly Data.

Comments & Questions

- *Angela Taylor*: This recommendation seems to be a blend between the Clinical Care and LTSS Subcommittees. Do we need further discussion between the two subcommittees? *Dr. Cherry*: The Clinical Care Subcommittee was focused more on training, but this is focused on implementation and how we train a workforce to

deliver the services. *Dr. Epstein-Lebow*: We are addressing antipsychotic use only in the Clinical Care Subcommittee. It may make more sense to have it at the highest level. This looks at where the barriers are.

- *Debra Cherry* will reformat the LTSS recommendations, include a forgotten section, and resend.

Non-Federal Members Vote

All members voted in favor of the recommendations as amended.

REFLECTIONS FROM RETIRING MEMBERS AND LOOKING FORWARD

Dr. Lamont announced that this is the last meeting for five members. In addition, Michelle Dionne-Vahalik took a new position and resigned. The six new members will be announced in September. The leadership model will change slightly so the Council will be led by two co-chairs: Ms. Brandt and Dr. Levey. Subcommittee chairs will be: Dr. Cherry, LTSS; Robert Egge, Clinical Care; and Dr. Hyman, Research.

Dr. Gitlin thanked Dr. Lamont, noting that the federal members do a lot of behind-the-scenes work. She then thanked Council members who have to understand the opportunities and limitations imposed by legislative rules and regulations.

She identified four key goals for the 2-year chair appointment:

- Enhance engagement of all members and more responsibility of subcommittee chairs/members.
- Link recommendations/activities to five goals/strategies/actions of the National Plan.
- Identify ways to be more impactful.
- Examine ways to systematically evaluate accomplishments and identify future directions.

Her recommendations were:

- Expand the reach of Advisory Council meetings.
- Require chairs and subcommittee chairs to formulate clear goals for what they want to accomplish and to clearly link meeting and speakers to evolving recommendations.
- Prepare for 2025 by evaluating what has been accomplished and what needs to be accomplished and provide a strong rationale for continuing the Advisory Council.

Key areas needing immediate attention (some have been addressed at previous meetings) are:

- Advance an infrastructure for treatment delivery.
- Projected capacity is insufficient to handle expected case load for treatment.
- A key constraint is limited capacity of dementia specialists for diagnosis and limited access to infusion centers to deliver treatment.

- Addressing capacity constraints needs to involve payment policy, regulatory requirements, workforce considerations, and capacity planning at national and local levels as well as ground awareness; development of quality indicators, etc.
- Advance pragmatic trials that offer the science to help advance an infrastructure.

Moonshot to Improve Quality of Life Now

We have enough evidence and enough recommendations to make a real difference, and a Moon Shot is an important metaphor for our work. It is ambitious, but not unobtainable. We can make a real difference within the next few years. This initiative must be multi-sectorial and coordinated and focus on dementia care to improve quality of life.

The four Disciplines of Execution to achieve our “wildly important goals” (WIGs) are:

1. Focus on the WIGs. Define a crucial goal and narrow the team’s focus to that goal.
2. Act on lead measures. Consistently carry out and track results on those high-leverage activities that will lead to the achievement of WIGs.
3. Keep a compelling scoreboard. Visibly track key success measures on a goal.
4. Create a cadence of accountability. Regularly and frequently plan and report on activities intended to move the measures on the WIG scoreboard.

Comments & Questions

- *Angela Taylor*. One aspect is loss of the life the PLWD built. What do they want to retain? To remain in the home they chose before they were sick. How do they continue to live the life they want instead of the life the disease imposes on them? This relates to how we serve this community from their diagnosis onward. What would we need to do to empower the person to stay home? What drives placement to long-term care? We need better tools to deal with behavioral changes to have fewer people in long-term care and that do not rely on the client to achieve them.

Reflections from Retiring Advisory Council Members

Dr. Epstein-Lubow spoke about having influence without authority and complying with the procedures for writing recommendations, process of communications, and the way content was presented. But, while being an influencer, he himself was influenced, especially by PLWD. He thanked everyone.

Ms. Taylor. For some 8 years, Ms. Taylor assumed care of her mentally declining father. She deeply appreciates the everyday person who brings the first-hand experience to the table, including the public commenters. She was glad to see that related dementias are included--we need to engage these people. Crosstalk among the subcommittees was essential. Subcommittees are quite small and might be enlarged. This Council’s work needs to continue beyond 2025.

Ms. Huling Hummel warns people that it will take eight interactions for her to get their faces and names fixed in her mind, and this is her eighth official meeting. She thanked

everyone for the opportunity to sit in this seat; it is not her seat but that of one of the 5.8 million other PLWDs. She knows the new person will be warmly welcomed as she was, and she encouraged Council members not to compare that person with her because all PLWDs are unique. She thanked members for their support, wisdom, guidance, and patience in navigating the Council experience. She recognized her travel companion, Marian Weisse, and said, "Don't talk about us without us."

Sowande Tichawonna thanked the Council for being recommended 4 years ago. At the time it seemed like forever and with a steep learning curve. Last year when he lost his mother, he posted on social media and realized how supportive that could be. He will continue his work by spreading what he learned on social media to expand to a diverse audience. He serves as a voice for those with Down syndrome. He thanked the current leadership for making this last year very smooth for him. He thinks the Council must address consistency in federal members coming and going. When the people change it is a challenge. He also thanked people who took the time to present public comments for their valuable insights.

CONCLUDING REMARKS

Dr. Lamont thanked everyone and adjourned the meeting at 4:28 p.m.

The next NAPA meeting will take place October 2019.

Minutes submitted by Helen Lamont (ASPE).

All presentation handouts are available at <http://aspe.hhs.gov/advisory-council-alzheimers-research-care-and-services-meetings>.

PARTICIPANTS

Advisory Council Members

Present

Arlene Bierman, M.D., Agency for Healthcare Research and Quality
Katherine Brandt, Massachusetts General Hospital
Debra Cherry, Ph.D., Alzheimer's Greater Los Angeles
Alex Chiu, Ph.D., U.S. Department of Veterans Affairs [*for Marianne Shaughnessy*]
Gary Epstein-Lubow, M.D., Brown University
Bruce Finke, M.D., Indian Health Service
Laura Gitlin, Ph.D., Drexel University, *Chair*
Richard Hodes, M.D., National Institute on Aging
Cynthia Huling Hummel, a person living with Alzheimer's disease, Elmira, NY
Bradley Hyman, M.D., Alzheimer's Disease Research Center
Becky Kurtz, Atlanta Regional Commission, Area Agency on Aging [*via telephone*]
Helen Lamont, Ph.D., Office of the Assistant Secretary for Planning and Evaluation,
U.S. Department of Health and Human Services
Allan Levey, M.D., Emory University
Sheri Ling, M.D., Centers for Medicare & Medicaid Services
Lisa McGuire, Ph.D., Centers for Disease Control and Prevention
Deborah Olster, Ph.D., National Science Foundation
Arne Owens, Office of the Assistant Secretary for Planning and Evaluation, U.S.
Department of Health and Human Services
Angela Taylor, Lewy Body Dementia Association
Sowande Tichawonna, caregiver, Washington, DC
Joan Weiss, Ph.D., Health Resources and Services Administration

Absent

Michelle Dionne-Vahalik, Texas Health and Human Services Commission
Billy Dunn, Food and Drug Administration
Robert Egge, Alzheimer's Association
Erin Long, Administration for Community Living, Administration on Aging
Anthony Pacifico, Ph.D., Agency for Healthcare Research and Quality

Public

Speakers

Carolyn Angus-Hornbuckle, J.D., National Indian Health Board

Mary French, M.S., Alzheimer's Association

Emma Nye, Office of the Assistant Secretary for Planning and Evaluation, U.S.
Department of Health and Human Services

Blythe Winchester, M.D., Cherokee Indian Hospital *[via telephone]*

Attendees

Dawn Berand

Diana Blackwelder

Erin Cadwalader

Molly Checksfield

Sara Cho

Rachel Conant

Sheritta Cooper Porter

Janice Cotter

Phil Cronin

Daniel Crown

Carla Danesi

Gloria Danesi

Elena Fazio

Mary Hogan

Judit Illes

Matthew Janicki

Nancy Jokinen

Chandra Keller

Seth Keller

Rohini Khillan

Ying-Yee Kong

Ian Kremer

Heather Menne

Melissa Michelson

Susan Peschin

Jennifer Pollack

Jaiden Presley

Morgan Presley

Kathy Service

Matthew Sharp

Eric Sokol

Maryanne Sterling

Winfield Swanson

Sarah Tellock

Dr. Thompson

Laura Thornhill

Courtney Wallen

Deidre Young