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

Washington, DC

October 26, 2015

Advisory Council Members in Attendance

- *Non-Federal Members Present*: Ronald Petersen (Chair), Laurel Coleman, Gary Epstein-Lubow, Laura Gitlin, Harry Johns, Myriam Marquez, Helen Matheny, Jennifer Mead, Sowande Tichawonna, Angela Taylor, Donna Walberg

- *Federal Members (or representatives) Present*: Richard Allman (VA), Susan Cooley (VA), Billy Dunn (FDA), Linda Elam (ASPE), Bruce Finke (IHS), Richard Hodes (NIA/NIH]), Shari Ling (CMS), Lisa McGuire (CDC), William Spector (AHRQ), Jane Tilly (ACL), Joan Weiss (HRSA), Mary Worstell (OASH)

- *Quorum present?* Yes

- *Advisory Council Designated Federal Officer*: Rohini Khillan (ASPE)

General Proceedings

At 9:03 a.m., Dr. Ronald Petersen called the meeting to order.

Dr. Petersen introduced himself, welcomed meeting participants and attendees, and highlighted the responsibility of the group to move forward in the area of Alzheimer's disease and related dementias by challenging each other and systems in place. He reminded the group that those living with and managing dementia have urgent needs, and the Council is obligated to work diligently and make meaningful progress.

Dr. Linda Elam, Deputy Assistant Secretary for Disability, Aging and Long-Term Care Policy, also welcomed meeting participants and encouraged a maintained focus on the Council's charge and the collaborative efforts that have emerged from Council activities. Dr. Elam acknowledged the multiple requests her office has received regarding remote access to council meetings. She reminded participants that a live webcast is available for each meeting and added that public comments are important to the council's work. Comments can be submitted and read during each Council meeting, even if the commenter is not present. Dr. Elam shared that her office is investigating possible remote-access options for future meetings; however, she noted several limitations (including the potential burden of maintaining a teleconference line for the full duration of the meeting, and the enforcement of the two-minute limit on public comments) that make remote access a challenge. Dr. Elam encouraged individuals to contact her directly with any questions, and assured the participants that the Office of the Assistant Secretary for Planning and Evaluation (ASPE) continues to work to determine the feasibility of a teleconference meeting option in the future.

Introduction of New Members

Dr. Petersen invited all members of the council to introduce themselves, including the six members for whom this was their first Council meeting:

- Gary Epstein-Lubow is a geriatric psychiatrist with experience in clinical care, psychosocial research, Alzheimer's-related policy development. He is also a family caregiver for a family member with dementia

- Laura Gitlin is a professor at the Johns Hopkins University and directs integrative care and aging in the School of Nursing. She works to develop and implement integrative care strategies, primarily for patients with moderate stages of dementia.

- Myriam Marquez is currently living with Alzheimer's disease caused by a hereditary genetic condition. She has worked in a variety of legal positions and currently serves on several Alzheimer's and dementia-related advocacy groups.

- Angela Taylor is the Director of Programs at the Lewy Body Dementia Association. Her work in the field began after becoming an advocate for her father, who was diagnosed with Lewy Body dementia.

- Sowande Tichawonna is an actor and filmmaker whose mother died of Alzheimer's disease in 2013. He hopes to become an effective advocate and storyteller on the nature of the disease, as well sharing his experience as a family caregiver.
- Donna Walberg serves on the Minnesota Board on Aging and is focused on developing seamless and person-centered service systems, including systems for persons with dementia. She is also a caregiver to her husband who was recently diagnosed with Alzheimer's disease.

Following Council member introductions, Charles McEnerney, Director of Executive Resources at the Department of Health and Human Services (HHS), led the swearing-in ceremony for the new Council members, confirmed that members had no additional questions, and then welcomed them to HHS.

Overview of Alzheimer's and Related Dementias

Dr. Petersen delivered a 30-minute presentation on the fundamentals of Alzheimer’s disease, as well as other related dementias, in order to align the Council on the issues at hand.

- Alzheimer’s disease is typically the “elephant in the room.” However, there are several other forms of dementia, and their pathologies can overlap, adding to the complexity of dementia diseases.

- Different forms of dementia can have unique hallmarks. For example:
    - Frontotemporal lobar degeneration initially presents with behavioral symptoms typically, and may include personality and/or language changes.
    - Dementia with Lewy bodies is associated with a variety of behavioral and motor symptoms.
    - Vascular dementia is caused by a blood vessel issue, but has a varied presentation depending on the type of vessel involved and the location in the brain.

- Alzheimer’s is an insidious and progressive disease for which early diagnosis based on neurologic exams alone can be difficult, as exams may largely be normal.

- Alzheimer’s is characterized as a disease in which amyloid plaques are deposited outside of brain cells, and Tau tangles are present within brain cells; hence, Alzheimer’s is referred to as a plaque-entangled disease. The presence of Tau tangles in the areas of the brain responsible for memory leads to the symptom of forgetfulness in Alzheimer’s disease.

- The current hypothesis on biological sequence of Alzheimer’s disease is:
    - Plaque proteins are deposited very early in the disease process, and at this time, normal cognitive function is still present.
    - Tau formation happens subsequently, and the Tau protein can be detected by magnetic resonance imaging (MRI).
    - At a later stage in disease, cognitive/memory symptoms develop.
    - Thus, there may be approximately 10-20 years between the start of biological processes in Alzheimer’s and the development of symptoms.

- The multi-year progression that leads to symptomatic Alzheimer’s disease provides an opportunity to intervene in the process and potentially halt or prevent the development of symptoms. Researchers are making progress in identifying biomarkers to use in monitoring progression of disease, and hopefully for detecting Alzheimer’s at a stage where interventions can have the greatest impact.

Dr. Petersen described and showed examples of various neuroimaging tools available for viewing the brain. He included images from individuals with normal function, with mild cognitive impairment (MCI), and with dementia in order to show comparisons at various stages of disease. The various imaging techniques are useful in identifying biomarkers, assisting in early diagnosis, and monitoring disease progression. For example:

- The region of the brain in which the Alzheimer's disease process starts is the medial temporal lobe; memory functions take place in this region. As disease progresses, areas of the brain begin to shrink, beginning with the medial temporal lobe. These changes are visible on MRI images.

- Positron emission tomography (PET) scanning, combined with radiolabeled glucose, allows for visualizing areas of the brain that are metabolically active; using this technique over time can reveal areas where function is lost due to disease progression.

- While it is clear that increases in plaque and tangle formation is associated with an increase in cognitive issues, it is more complex in the real world. For example, an individual may have cognitive symptoms, but a normal brain scan, and a cognitively normal person may show evidence of problematic brain changes on a scan.

- A large multi-center study of approximately 18,000 people is ongoing to help determine how neuroimaging of individuals with early signs of Alzheimer's disease will affect them in the long term. This study is being funded by the Centers for Medicare and Medicaid Services (CMS).

- The clinical and basic research fields have made progress in using imaging to identify very early stages of Alzheimer's, including "pre-clinical" disease in which individuals have biologic characteristics of disease, but are clinically normal with no symptoms.

Dr. Petersen shared an overview of the currently available treatment options for Alzheimer's and described the different therapeutic approaches that may be useful in treating the disease.

- Memantine was Food and Drug Administration (FDA)-approved to treat Alzheimer's in 2003; however, no new agents have been approved since then. Cholinesterase drugs and NMDA antagonists are also in use for Alzheimer's, but none of these can alter the progression of disease.

- *Primary prevention* of Alzheimer's is focused on preventing the disease processes before they begin and would benefit individuals who have no symptoms or biological signs of disease. Primary prevention therapies for

Alzheimer’s are not currently available, but in the future, could include a preventive vaccine.

- *Secondary prevention* of Alzheimer’s is targeted for individuals who have demonstrated early signs of disease or some biological indication of Alzheimer’s. These approaches would be aimed at halting the disease process and preventing progression and worsening of symptoms. Immunotherapies that use antibodies to treat Alzheimer’s are currently being evaluated, as are inhibitors of beta and gamma secretase, enzymes that generate the amyloid protein that leads to Alzheimer’s.

- *Symptomatic treatments* are able to help address disease symptoms such as cognition. They typically are effective for a period of time, but then lose effectiveness because the disease continues to progress and symptoms worsen.

Several areas of Alzheimer’s prevention are currently being studied in clinical trials. These reflect only a portion of clinical studies underway for Alzheimer’s and related dementias.

- The Dominantly Inherited Alzheimer’s Network Trial Unit is investigating prevention approaches in individuals with an inherited form of Alzheimer’s disease, which occurs in 1% of all Alzheimer’s cases.

- The Anti-Amyloid Treatment in Asymptomatic Alzheimer’s trial is studying secondary prevention in individuals who are clinically normal, but have amyloid protein present in their brains.

- The Study of Nasal Insulin to Fight Forgetfulness trial is researching the benefit of intranasal insulin on Alzheimer’s symptoms in individuals with MCI or dementia.

- There are increasing data that lifestyle modification, such as increasing physical activity, can favorably impact the progression of and symptoms associated with Alzheimer’s.

Dr. Petersen concluded by summarizing the clinical spectrum of Alzheimer’s disease and dementia, and their components. In addition to amyloid formation, Tau tangles, vascular disease, several other biological factors likely contribute to dementias. Furthermore, our ability to detect these factors or biomarkers, fully understand their origin, and develop effective therapies against them is evolving--but much more information is needed. Significant progress has been made to date; however, increased funding is needed to accelerate the collective efforts.

National Plan to Address Alzheimer's Disease and Strategic Planning at HHS

Sarah Potter from the Strategic Planning Team at HHS provided a brief overview of the strategic planning process employed by agencies and teams across HHS. The National Plan to Address Alzheimer’s Disease is a component of the overall HHS Strategic Plan.

- There are approximately 150 strategic plans across HHS that vary in scope, sponsor, and topic area. From an overall agency perspective, it is important to ensure that all strategic plans are well-aligned with the HHS strategic plan.

- The HHS Strategic Plan for fiscal years 2014-2018 has four main goals: (1) Strengthen Health Care; (2) Accelerate Scientific Knowledge and Innovation; (3) Advance the Health, Safety, and Well-being of the American People; and (4) Ensure Efficiency, Transparency, Accountability, and Effectiveness of HHS Programs.

- The priorities identified in the National Plan to Address Alzheimer’s Disease are in close alignment with the agency-level strategic goals:
    - *Goal 1*: Prevent and Effectively Treat Alzheimer’s Disease by 2025 (aligned with HHS goal 2).
    - *Goal 2*: Enhance Care Quality and Efficiency (aligned with HHS goal 1).
    - *Goal 3*: Expand Supports for People with Alzheimer’s Disease and their Families (aligned with HHS goal 3).
    - *Goal 4*: Enhance Public Awareness and Engagement (aligned with HHS goal 3).
    - *Goal 5*: Improve Data To Track Progress (aligned with HHS goal 4).

- Successful strategic plan development is dependent upon the identification of realistic goals that can be translated into meaningful actions--strategic plans are “blueprints for action.” This requires being mindful of not including more goals or plans than are actually feasible, despite the natural tendency to do so. Six steps can help inform a strategic plan and ensure that the goals within it can be achieved:
    - *Identify the problem*--Name the problem and determine what it will look like over time. Understand why it is a problem and determine if it can be influenced through planned actions.
    - *Identify the evidence*--Determine if there is evidence that the planned actions will lead to the desired outcomes, and if not, identify a plan to evaluate the success of the planned actions.
    - *Prioritize actions*--Select a manageable set of actions that can be accomplished and prioritize them in a way that can maximize efforts. This is often the most difficult step in strategic planning.
    - *Implement actions*--Determine which if the actions can truly be implemented based on resources, time, and money, and only include those in the final plan.

  - *Measure progress*--Progress with plan activities should be measured and monitored to understand when actions are leading to good results, and identifying when it may be time to re-evaluate a strategy.
  - *Mitigate risks*--Every strategic plan is associated with some degree of risk, such as decreased funding levels or unsuccessful implementation of an action. Risks should be anticipated where possible, identified, and mitigated so that efforts can be adjusted as needed.

- Once a strategic plan has been created, its implementation should be effectively managed by: maintaining a single point of contact for plan coordination; being realistic about plan timelines and focusing on what can be accomplished in one year; being realistic about available resources to support the plan, and; assessing and reporting regularly on progress.

Discussion

- Given the charge of the Council, it may be difficult to distinguish between what should be incorporated into the National Plan versus what remains an aspirational recommendation. The strategic plan is designed to operate within the current federal budget; however, aspirational goals that may exceed available resources are not discouraged, but should not be included in a strategic plan if they cannot be accomplished.

- The recommendation generated from the Council can and should exist as a distinct document from the strategic plan, although they should be compatible.

- The Council members will be provided with examples of strategic plans and reporting approaches from other entities within HHS to supplement the information shared during the presentation.

Overview of the NAPA Legislation and the Charge of the Council

Dr. Petersen provided the council with a historical perspective on the National Alzheimer's Project Act (NAPA) legislation, as well as the roles and responsibilities outlined within the law.

- NAPA was passed by Congress in 2010, and in 2011 it was signed into law and the Advisory Council was appointed. The first National Plan was created in 2012; it has been updated each year, and annual updates are required through 2025.

- NAPA legislation uses the term "Alzheimer's disease" in its title and elsewhere; however, the intention of the Act is to include and address all types of dementia.

- NAPA charges the HHS Secretary to:
    - Create and maintain the National Plan.
    - Coordinate Alzheimer's research and services across federal agencies.
    - Accelerate the development of treatments.
    - Improve early diagnosis and coordination of care and treatment.
    - Ensure the inclusion of ethnic and racial populations at higher risk.
    - Coordinate with international bodies.

- The NAPA Advisory Council on Research, Care, and Services consists of 12 non-federal members who are patient advocates, caregivers, health care providers, representative of state health departments, researchers, and representative of voluntary health associations.

- Federal agency representation on the Advisory Council includes: the Center for Disease Control and Prevention (CDC), Administration on Aging, CMS, Indian Health Services (IHS), National Institutes of Health (NIH), Office of the Surgeon General, National Science Foundation, Department of Veterans Affairs (VA), FDA, and Agency for Healthcare Research and Quality (AHRQ).

- The overall goal of the NAPA is to effectively treat, prevent, delay onset of, and slow progression of Alzheimer's disease by 2025. While effective prevention of Alzheimer's may pose a significant challenge, successful approaches to delaying and slowing progression of disease will have a dramatic impact on health outcomes and the burden of disease. Even if curative therapies are not within reach, delaying onset and delaying progression have the potential to significantly reduce the number of cases of Alzheimer's disease by 2050.

Discussion

- Measuring and achieving delay of progression in individuals with asymptomatic disease will be challenging; however, looking at epidemiological data from the National Institute on Aging (NIA) studies and tracking incidence rates over time may be a useful approach.

- While the term may be somewhat limiting, "management" of Alzheimer's must include clinical and long-term care services in addition to treatment.

- The Advisory Council can and should make recommendations as it sees fit, even if those recommendations require funding beyond what is currently allocated. While HHS and other federal parties cannot request actions that require legislation changes, the Council and other non-federal stakeholders can. Collaborative efforts to advance the recommendations put forth by the Council are needed to make progress. Increased advocacy by experts and the general public are critical to elevating the issue of Alzheimer's disease and related dementias in the minds of policymakers.

- The federal workgroups formed under NAPA serve to convene various federal agencies to coordinate activities and support generation of the National Plan.

Overview of the National Plan and the Process for Recommendations

Rohini Khillan presented a summary of the National Plan and the process through which Council recommendations are generated and provided to Congress.

- National Plan creation is a multi-step process led by federal workgroups that discuss: recommendations from the Advisory Council, actions undertaken by various HHS agencies, and outcomes and milestones achieved. This information is compiled and formatted by ASPE, which then assembles the formal plan and submits it for review and finalization. Once the plan receives approval from HHS clearance, the Secretary signs off, and the document is then sent to Congress.

- In 2015, the updated Plan was revised to reflect feedback that previous plans were too lengthy and difficult to read. The new format is structured to reflect a progress report rather than a list of activities.

- There are 121 activities reported in the current National Plan, creating a lengthy document. ASPE is working to streamline the capture of these activities to improve readability and to make it more succinct. Additionally, the list will be edited to reorganize activities, consolidate them where appropriate, and clearly identify next steps.

- The 2015 recommendations provided by the three subcommittees (Research, Clinical Care, and Long-Term Services and Supports) decreased to 12, down from 27 recommendations in 2014. This reduction reflected distillation by the subcommittees and made the overall document much easier to read. Recommendations were sent to 17 members of Congress spanning both political parties, including the chair and ranking member of several committees, and to senators with a demonstrated interest in dementia.

The **Research** subcommittee recommendations for 2015 were:

1. *The 2015 National Plan must provide a robust, comprehensive, and transformative scientific roadmap for achieving the goal of preventing and effectively treating Alzheimer’s disease by 2025.*

2. *The urgent need for increased annual federal research funding sufficient to meet the 2025 goal remains a top priority.*

3. *In developing their professional judgment budget (or “Bypass Budget”), the NIH should identify the total science-driven funding needs for the budget year and also address the scale of needs anticipated through 2025.*

4. *The 2015 National Plan should outline specific contributions being made by the Federal Government to the international initiatives needed to fulfill the commitments made by the Federal Government at the 2013 Dementia Summit in London.*

The Research subcommittee recommendations were appreciated by the Council, particularly the need to define a clear path forward to achieve the goals of the National Plan. Additionally, the NIH presentation of the Professional Judgment Budget, provides an opportunity to have candid discussions about the funding levels required to achieve the National Plan goals by 2025.

Recommendations from the **Clinical** subcommittee were:

1. *HHS should encourage efforts to foster dementia-friendly communities.*

2. *Efforts should be made to evaluate feasibility of measuring care quality and effectiveness by using patient-centered goals.*

3. *Works needs to be done to ensure both the quality of life and the quality of care for persons living with advanced dementia and their families across care settings.*

The Clinical subcommittee recommendations related to comprehensive management of individuals with Alzheimer's including supporting improvements in the communities in which people live. The Administration for Community Living (ACL) administers grants that support the development of dementia-friendly communities and several states/localities are making great progress. It will be important to identify metrics of success in this area, as well as clearly attribute responsibilities to various HHS agencies tasked with fulfilling these goals. There are challenges in providing adequate resources for those with advanced dementia and their caregivers, in part, due to reimbursement practices. For example, CMS coverage of certain services requires that the person with Alzheimer's receive the service; however, the clinical services provided may actually be directed toward a family member or caregiver.

The **Long-Term Services and Supports (LTSS)** committee recommendations were:

1. *HHS should support state initiatives to provide robust, dementia capable LTSS systems. Approximately 18 states are implementing dementia-capable systems. Additionally, collaborations with state governors are being explored for possible development of assessments of these systems.*

2. *HHS should encourage federal agencies to include research on LTSS that addresses dementia capability in their research agendas. ASPE released the National Survey on Caregiving (NSOC) as part of the National Health and Aging Trend Study. Data are now available on caregivers and studies are underway on*

caregiver networks, stresses, facilitators, duration of caregiving, as well as secondary caregivers and other resources.

3. *CMS should redesign Medicare coverage and health care providers' reimbursement to encourage diagnosis, support care planning, and active referral to LTSS. Because Medicare benefits are statutorily defined, it is difficult to extend benefits to the caregiver of the beneficiary. Additionally, work is being done to incorporate billing codes for advanced care planning that support health care provider engagement with long-term care of individuals with dementia.*

4. *HHS, state lead entities, and providers should assure that caregiver health and behavioral health risk is assessed and addressed regularly. The NSOC has provided some initial information to inform projects that address the needs of caregivers.*

5. *Congress should assure adequate funding for LTSS. A colloquium on long-term financing was held in July 2015 and several innovative models were discussed.*

Summary and Discussion

- The Federal Government acknowledged making dedicated efforts to increase transparency on how Council recommendations are reviewed and addressed in the National Plan.

- Several steps aimed at increasing the efficiency and effectiveness of the recommendations process were discussed, including: increasing collaboration among public and private sectors, crafting succinct recommendations, categorizing recommendations for increased organization and readability, and inserting the recommendations into the National Plan as an appendix so that they are formally linked to the plan.

- Inclusion of more real-world stories may increase the impact of recommendations and bring greater awareness of the issues.

- It was proposed that, in the future, individual subcommittees discuss recommendations by reviewing the issue, identifying potential barriers, and proposing ways to address them and move forward. Subsequently, the subcommittee findings can be presented to the larger Council via written or verbal summary.

- In the future, a standardized format for recommendations may be developed and used to streamline Council activities.

- The increased transparency provided by ASPE and the federal Council members was beneficial to the group and should enhance activities moving forward.

- It is important to remember that the National Plan is truly a **national** plan, not a **federal** plan, so seeking opportunities for collaboration across many sectors should remain a priority.

Because this was the first meeting for the new members, the Council dismissed the public participants for a brief closed-door procedural discussion during the lunch break. The Council then received an HHS-required ethics training before again allowing public access.

Public Input

Rohini Khillan moderated the public comments portion of the meeting. She shared that ASPE welcomes public feedback related to the Council activities at any time.

Nine members of the public presented testimony either in person or by email and included: people living with dementia, family members and caregivers of people with dementia, and representatives from the National Alliance for Caregiving, the Alzheimer's Foundation of America, Leaders Engaged on Alzheimer’s Disease, the Association for the Frontotemporal Dementias, the National Task Group on Intellectual Disabilities and Dementia Practices, and the National Certification Board for Alzheimer's Care. The public comments provided perspectives on the following:

- Incorporating international efforts in the work of the Advisory Council can increase exposure to and awareness of successful models and best practices that may not be in use in the United States, but may be adapted for application here. Many countries are leading national-level efforts to address the needs of their aging populations.

- November is National Alzheimer’s Awareness Month and the Alzheimer’s Foundation of America is hosting a national Memory Screening week November 1-7, 2015. While memory screenings are not a diagnosis of any condition, they can help identify individuals who may benefit from additional clinical evaluation.

- The appointment of a Council member representing the Lewy Body Dementia Association is an important step forward; however, an increased focus on Council participation with expertise in non-Alzheimer’s related dementia is needed.

- A new $5 million initiative has been launched to promote research on biomarkers on diseases related to frontotemporal dementia.

- Following recommendations made earlier in 2015, a multi-stakeholder summit focusing on Alzheimer’s and related dementia care and services is planned and will operate in a similar fashion to the biomedical research summits that has informed both federal and non-federal actions toward the 2025 plan. A national summit is planned for winter 2015/2016.

- Demands for increased federal funding for Alzheimer's and related dementias need to be maintained, even in light of overall NIH funding decreases.

- Reasonable accommodations need to be made by ASPE/HHS for public participation in Council meetings for those who may not be able to travel or participate via email-based comments, especially those living with dementia.

- The Council should increase and sustain a focus on the care and services for people living with dementia. Brief and isolated trainings are insufficient to adequately train those providing care; thus, more funding and programming are needed.

- The work conducted by the Council has had significant impact on the increased awareness of the specific issues facing those with both Down syndrome and dementia, including hypothyroidism, reduced body weight, and falls.

Federal Workgroup Updates

Clinical Services

- The Center for Medicare and Medicaid Innovation (CMMI) provides an opportunity to test new care and payment models, evaluate results and advance best practices, and engage a range of stakeholders for additional model development. There are valuable lessons to be learned from these innovations, even from those that may not ultimately be implemented. There are several projects related to dementia, either directly or indirectly, currently being tested through innovation projects.

- The first round of the Health Care Innovation Awards (HCIA) funded 107 participants from 2012-2015 at $1 million to $3 million each. Awardees have completed their year one annual reports and second-year reports are expected in early 2016. Round one projects targeting persons with dementia included (but are not limited to): developing holistic and coordinated care for persons with dementia, training family caregivers and direct-care workers to improve long-term care, and developing person-centered and family-centered program for persons with dementia.

- During the second round of HCIA funding, proposals addressing "care for populations with specialized needs" was identified as one funding priority. Thirty-nine awards were granted for the 2014-2017 cycle, and two specifically focused on Alzheimer's disease. All annual reports from HCIA awardees will be made available on the CMMI website.

- Strengthening person-centered and family-centered care is a major goal of CMS quality strategies, and reflects national HHS strategy, so significant work will be done on these efforts.

- CMS has contracted with the National Quality Forum (NQF) to work on quality measures in areas such as nursing homes, as well as in home and community services. CMS/HHS/ASPE/ACL collaborated on a project put forth by the NQF to assess home and community-based services.

- The Medicaid Innovation Accelerator Program addresses substance abuse, long-term care, physical/mental health integration, and complex care. New opportunities for innovative approaches for Medicaid beneficiaries with dementia are emerging, as they qualify as "*beneficiaries who, because of their health and/or social conditions, are vulnerable to experience high levels of costly and often preventable service utilization, and whose care patterns and costs are potentially impactable*."

- Telehealth services are available under CMS and the covered services differ by state, context, and can change over time. The introduction of the Medicare chronic care management services in 2015, there may be opportunities for additional procedural codes for telehealth-based psychotherapy, or prolonged visits.

- While not discussed in the National Plan explicitly, hospice care is relevant to persons with dementia. Effective January 1, 2016, two hospice care refinements will go into effect. (1) Hospice care for Medicare beneficiaries will provide for two home-care rates to cover the first 60 days of care, and then care exceeding 60 days. (2) CMS will provide an add-on payment to promote skilled visits at the end of life, and compensate that service provision accordingly.

- CMS has an Alzheimer's Disease and Related Dementia "affinity group" in which staff from every CMS center participate to identify and share existing programs and leverage what is needed in a coordinated fashion.

- The Health Resources and Services Administration (HRSA) Geriatric Workforce Enhancement Program is a compilation of all four of their geriatric programs. Previously, these programs were Title 7 and Title 8 programs. The newly structured program retains the Geriatric Education Center. Program grantees must have at least one primary care partnership and at least one community-based organization (CBO) partnership. Currently, $35.7 million has been awarded to 44 grantees who are in partnership with 73 CBOs and 106 primary care sites. Over $5 million of these funds are supporting Alzheimer's disease and related education/training. Most awardees are schools of medicine and nursing; however, the types of partnerships and target populations served vary widely.

- In 2013, funding from ASPE helped support a Medscape educational module on Alzheimer's disease, which has reached over 63,000 health professionals. Currently, HRSA is partnering with the Office on Women's Health on a Medscape article focusing on Alzheimer's in the context of other chronic medical conditions; the expected release date is September 2016. Both Medscape offerings provide continuing education credit.

- In response to a recommendation from the Advisory Council, HRSA is developing a unified Alzheimer's disease curriculum to be completed in September 2016. The curriculum will be designed for both modular use and use as a full start-to-finish program. The curriculum will be built upon the Alzheimer's Preparing Minnesota Communities training program.

Long-Term Services and Supports (LTSS)

- For the first time, permanent Healthy People goals related to dementia are included in the national public health goals outlined in Healthy People 2020 (HP2020).

- Despite funding limitations, ACL has been able to continue support of the Alzheimer's Association, awareness campaigns, and the National Alzheimer's Call Center. Furthermore, 18 states are becoming dementia-capable, with thousands of providers and caregivers trained through ACL-sponsored programming. ACL is also now awarding projects under the Alzheimer's Disease Initiative Special Supportive Services grants, which are focused on translating evidence-based practices to address the needs of a specific population.

- ACL grant recipients vary by type of organization and location, and include: the Alzheimer's Association, the Benjamin Rose Institute, which consults with states as they implement evidence-based services, the National Task Force Intellectual Disabilities and Dementia Practices, and the United Way.

- ACL has a long-term care ombudsman training program to provide education to those managing advocacy and other efforts for persons with dementia who do not have a caregiver or family representative; this program will be evaluated in 2017.

- In 2015, a "What is Brain Health?'" campaign was launched by ACL with the goal of increasing awareness and dialogue among the general public about cognitive health and dementia. Targeted social media efforts were used to determine the drivers and barriers to the campaign.

- CDC released a public health road map in collaboration with the Alzheimer's Association that shares recommendations promoting cognitive health and helping address the needs of those with cognitive impairment. Additionally, CDC awarded two cooperative agreements, one with the Alzheimer's Association and another with The Balm in Gilead--a faith-based group that focuses on the African-American community.

- CDC is planning to release a national report on care giving and cognitive impairment in the United States based on new modules included in the Behavioral Risk Factor Survey, the largest telephone survey in the world.

- CDC and NIH/NIA co-chaired the HP2020 dementia work group that led to plans to track rates of preventable hospitalizations among persons with dementia, as well as the number of persons who are aware of their dementia or cognitive impairment.

- In 2014, CDC funded the Healthy Brain Research Network comprised of five sites working to support implementation of the public health road map recommendations. In 2015, a sixth site was funded, and the network now includes: the University of Washington, Oregon Health Sciences University, the University of Arizona, the University of Chicago, the University of Pennsylvania, and the University of South Carolina.

- As part of national quality strategy efforts, CMS reported a decline in antipsychotic use in long-term nursing facilities to 18%, demonstrating an improvement at the care facility, and identifying a need to address the issue beyond nursing homes. CMS has also launched a survey to capture data on residents of long-term facilities who are at risk for an adverse drug event.

- Staffing of care facilities is also being captured by CMS in terms of turnover rates and appropriateness of staff level given the population within a facility--these assessments will be mandatory by July 2016.

- The CMS Medicare-Medicaid Coordination Office is collaborating with the Innovation Center to evaluate seven implementation projects aimed at improving the health of long-stay nursing home residents, many of whom have Alzheimer’s or related dementias.

- IHS has launched the Indian Country Initiative, a public-private partnership to support training and certification, and penetrate tribal communities through public health or community health professionals, tribal aging networks, or senior centers.

- There has been increased awareness and acceptance of dementia as a topic of interest at national tribal or Indian health meetings in recent years, reflecting tremendous progress and expanded opportunities to increase efforts and improve outcomes for persons living with dementia and their caregivers.

- IHS participates in a monthly LTSS webinar that is aimed at promoting partnerships between tribes and their local and state Alzheimer's Association chapters.

- NIH has recently issued funding announcements related to basic and translational research on caregivers of persons with Alzheimer's disease--work aimed at improving patient outcomes and alleviating caregiver burden.

- NIH, in partnership with CDC and ACL, is leading an annual webinar series covering new research findings in dementia. The upcoming November 17, 2015 webinar will cover caregiving issues with a focus on technology. Up to 1,400 people have been registering for the webinars, and up to 70% attendance has been observed.

- NIH has partnered with the VA and ACL to provide services to veterans who have cognitive disabilities in addition to physical disabilities; approximately 1,400 veterans have been served by this initiative to date.

Discussion

- Receiving approval for hospice care for persons with advanced dementia remains a challenge, in large part due to the poor prognostic indicators in dementia and the requirement for an expected lifespan of six months or less. The council agreed that identifying additional measures (e.g., comorbidities, weight loss) that could support engagement of hospice would be helpful; however, the six-month window is statutorily defined.

- Patient-Centered Outcomes Research Institute (PCORI) database includes over 75 million people across a wide spectrum of diseases. There is currently a PCORI project focused on dementia and this database may be an important resource for dementia-related work.

- Strategic efforts should be taken to publicize and disseminate Medscape and related activities to ensure broad reach and awareness by intended audiences.

- Training on the needs of persons with dementia should go beyond caregivers and providers; community members, first responders, and others need to be education to promote safer and more understanding environments.

- The Resources for Enhancing Alzheimer's Caregiver Health Program was a conventional multi-site academic randomized clinical trial support by NIA that has been implemented by many agencies, including VA, IHS, and ACL. The program has great promise for adaptation by many other agencies and organizations.

- The language used to described Alzheimer's disease and related dementias needs to remain as comprehensive as possible, as the frequent use of just

"Alzheimer's disease" can inadvertently imply efforts or interests more narrow in scope than is actually intended.

- The fact that Minnesota is often considered a "flagship state" with respect to dementia capability is a testament to the funding and support provided by federal and non-federal partners and support and has led to permanent funding commitments from the state legislature.

Discussion of the NIH Bypass Budget

Dr. Richard Hodes from NIA facilitated a discussion on the NIH bypass budget and Council subcommittees reported their recommendations for comment on the budget.

- The bypass budget is a mechanism by which NIH can communicate its view on budgetary requirements and submit budget proposals directly to the President for review and transmittal to Congress. The bypass budget identifies NIH's goals and the required levels of funding needed to meet those goals. The Alzheimer's Accountability Act charges the Secretary and the Advisory Council with reviewing and commenting on the bypass budget.

- The bypass budget was informed by several key meetings, including the: 2012 Alzheimer's Disease Research Summit, 2013 meeting on Alzheimer's Disease-Related Dementias: Research Challenges and Opportunities, 2013 meeting on Advancing Treatment for Alzheimer's Disease in Individuals with Down Syndrome, and the 2015 Alzheimer's Disease Research Summit. Thirteen NIH institutes and centers helped to prioritize areas of the budget, as well as highlight scientific gaps that need to be addressed.

- Alzheimer's disease has been prioritized within the NIH budget in recent years--between 2011 and 2015, the overall NIH budget decreased by 2%; however, the funding for Alzheimer's related dementia research increased by 42%.

- The baseline estimates for the 2016 fiscal year budget are (*Note: there are overlaps among the categories listed below; total funding estimates are lower than the sum of estimates below*):
    - Alzheimer's Disease--$638,000,000.
    - Vascular Cognitive Impairment/Dementia--$ 46,000,000.
    - Frontotemporal Dementia--$38,000,000.
    - Lewy Body Dementia--$15,000,000.

- The research categories listed in the bypass budget reflect efforts of the Alzheimer's Association and NIA to create the Common Alzheimer's Disease Research Ontology (CADRO). CADRO helped to identify gaps and priorities in the field and has now expanded into the International Alzheimer's Disease

Research Portfolio, which is publically available and a useful organizing tool for budget construction.

- The fiscal year 2017 bypass budget proposes an increase of $323,355,000. By law, there is an opportunity to request additional funds each year until 2025.

- In anticipation of a possible funding increase for fiscal year 2016, several funding opportunities have been issued to capture research efforts aligned with the priorities identified, including (but not limited to): health disparities, caregiving research, epidemiology, molecular and biological mechanisms of Alzheimer's disease, and early and later-stage treatment of Alzheimer's disease.

- NIH, AHRQ, and the Institute of Medicine are implementing a two-part assessments of the science of prevention in Alzheimer's disease, amnestic MCI, and age-related cognitive decline. The project will consist of a literature review of evidence-based practices reviewed by an expert panel to make recommendation on effective strategies and existing knowledge gaps. Public input will be solicited during this study.

Discussion

- The three Advisory Council subcommittees has reviewed and discussed the bypass budget and presented comments; the budget was supported by all committees, with minor comment.

- The Research subcommittee commented: "*The Advisory Council on Alzheimer's Research, Care and Services strongly endorses the National Institutes of Health Bypass budget Proposal for Fiscal Year 2017. The Council urges Congress to provide the funds identified by NIH to achieve the National Plan to Address Alzheimer's Disease goal 'to prevent and effectively treat Alzheimer's disease by 2025'.*"

- The Clinical subcommittee commented: "*The clinical care subcommittee of the Alzheimer's advisory board confirms our support for the NIH professional bypass budget. This investment is crucial to help scientists find an effective treatment for Alzheimer's disease.*"

- The LTSS subcommittee commented that "*Separate priority should be given to research on the most effective assessments of cognitive impairment, strategies to support caregivers, reduce caregiver stress and mitigate health risks, long-term services and supports in the community, array of living options to maximize quality of life, options for payment for long-term services and supports.*"

- After lengthy discussion, it was recommended that Council consider a simple endorsement of the budget rather than specifying how funds should be expended, as noted by the LTSS subcommittee. This course of action was recommended to reduce any confusion or perceived lack of support from the Council when the comments are communicated to Congress. A motion was made to endorse the bypass budget and send comments from the Research subcommittee (with quotation marks removed), and the addition of “treat and manage Alzheimer’s disease”. The motion was passed.

Concluding Remarks

Dr. Petersen thanked the Council members and charged them with generating recommendations for the 2016 National Plan in advance of the next meeting, tentatively scheduled for Tuesday, January 19, 2016. New members will be contacted by ASPE and/or Dr. Petersen to determine on which subcommittee(s) they would like to participate.

The meeting adjourned at 5:11 p.m.

Minutes submitted by Rohini Khillan (ASPE).
All presentation handouts are available at http://aspe.hhs.gov/advisory-council-alzheimers-research-care-and-services-meetings.