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

Washington, DC

October 15, 2012

Advisory Council Members

Non-Federal Members Present: Ronald Petersen (Chair), Laurel Coleman, Eric Hall, David Hoffman, Harry Johns, Jennifer Manly, Helen Matheny, Julie McMahon, Laura Trejo, George Vradenburg, Geraldine Woolfolk, *Via Phone:* David Hyde Pierce

Federal Members Present: Lynda Anderson (Centers for Disease Control and Prevention [CDC]), Susan Cooley sitting in for James Burris (Veterans' Affairs [VA]), Regina Benjamin (Surgeon General), Richard Hodes (Nation Institutes of Health [NIH]), Russell Katz (U.S. Food and Drug Administration [FDA]), Shari Ling (Centers for Medicare and Medicaid Services [CMS]), Donald Moulds (Office of the Assistant Secretary for Planning and Evaluation [ASPE]), William Spector (Agency for Healthcare Research and Quality [AHRQ]), Joan Weiss (Health Resources and Services Administration [HRSA]), Jane Tilly (Administration for Community Living [ACL])

Quorum present? Yes

Advisory Council Designated Federal Officer: Helen Lamont (ASPE)

Other Federal Official Present: Marian Scheinholtz (Substance Abuse and Mental Health Services Administration [SAMHSA])

Proceedings

- Meeting called to order at 9:10 a.m. by Chair, Dr. Ronald Petersen.
- Advisory Council members introduced themselves.
- Dr. Peterson provided an overview of the agenda and outlined the purpose of the meeting. The three subcommittees of the Advisory Council (Long-Term Services and Supports, Clinical Care, and Research) met prior to the meeting to review recommendations to be included in the National Plan to Address Alzheimer's Disease to determine whether the recommendations are appropriate, comprehensive, and up to date. The primary purpose of today's meeting is to finalize the recommendations for the January meeting of the Council. Today's meeting will include an update from the Federal workgroups, discussion of public-private partnerships, consideration of overarching goals and priorities for 2013, and subcommittee reports on the recommendations, followed by public comments.

Updates From Federal Workgroups

- Dr. Hodes presented an update from the Research Subgroup.
    - The National Institute on Aging (NIA) and the Alzheimer's Association have established an International Alzheimer's Disease Research Portfolio (IADRP) that categorizes areas of Alzheimer's research according to the common language used by investigators. The ultimate goal of IADRP is to enable funders of Alzheimer's research to coordinate their investments, leverage resources, encourage collaboration, and identify research gaps and unnecessary duplication. IADRP also will provide a metric to chart the progress of research on Alzheimer's disease. The relatively user-friendly database is available on the website (iadrp.nia.nih.gov).
    - The White House has proposed $80 million in additional Alzheimer's disease research funding in 2013. Solicitations call for research proposals in genetic analysis, target identification and validation, Phase I clinical trials for Alzheimer's disease therapeutics, and prevention trials.
    - Clinical trial enrollment was announced at the May 1-2, 2013, workshop on Alzheimer's disease–related dementias.
    - A workshop on Down Syndrome and Alzheimer's disease research was held in September 2012.
    - NIA and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development have begun planning another workshop for 2013.
    - In response to a question, Dr. Hodes stated that leveraging investments in Phase I and prevention trials with private sector money has been quite effective.

- Dr. Shari Ling delivered a progress report from the Clinical Care Subgroup.
    - Seven assessment tools are used in a variety of outpatient settings, including the Medicare Annual Wellness Visit (AWV), to assess cognition.
    - The Medicare AWV is designed to evaluate persons, not specific conditions. If a person is expected to have cognitive impairment, this finding must be taken into consideration with other modifiable risk factors that might influence the person's outcome. For example, likely cognitive impairment detected through these tools may be the result of cardiovascular disease, not Alzheimer's disease.
    - Identification of cognitive impairment during the AWV is merely a first step, and a physician may want to rule out the potentially reversible causes of cognitive impairment such as depression.
    - Programmatically relevant dementia care guidelines and measures exist along with the Physician Quality Reporting System (PQRS) for dementia measures.
    - Public-private partnerships have worked to improve behavioral health for persons in long-term care facilities, in particular, regarding the use of antipsychotics. The preferred road to diagnostic coverage is to provide adequate evidence that the incremental information obtained, by new diagnostic technology compared with alternatives, changes physician recommendations, which will result in changes in therapy that improve clinically meaningful health outcomes in Medicare beneficiaries.
    - Discussion following Dr. Ling's presentation included the following points:
        1. CMS should encourage the evaluation and exclusion of potentially reversible causes, but services must follow screening.

2. Are there any tools that can be administered by the patient without a clinician? If the tools can be administered electronically and the information imported into an electronic health record, then the longitudinal data could be delivered in a validated way to the scientific community. The potential and the challenges of these data would need to be considered.
3. The seven tools are not exclusive. Family report and patient self-report also are important to the detection of cognitive impairment.
4. Language accessibility is an important issue involved in cognitive assessments, as are the issues of screening versus detection, cross-cultural awareness, low literacy, and socioeconomic status.
5. Risk factors and risk assessment, including demographic epidemiologic lifestyle variables that identify high-risk individuals should be used to help determine which individuals merit more screenings.

- Dr. Tilly presented a progress report from the Long-Term Services and Supports Subgroup. Dr. Tilly covered three areas: (1) the Specific Populations Task Force, (2) education/outreach efforts, and (3) interventions for persons with dementia and their caregivers
    1. The Specific Populations Task Force involves three subgroups: (1) individuals with younger onset dementia, (2) racial/ethnic minorities, and (3) individuals with intellectual disabilities such as Down Syndrome. The task force convened in August and has had a number of meetings involving caregivers and key stakeholder groups. A key finding is the need for primary care practitioners who interact with these populations to heighten their awareness of dementia and acquire training and education.
    2. The Alzheimers.gov Web site now includes a Web page on Down Syndrome and has been updated with Spanish-language materials.
    3. Dr. Tilly reported on a public-private partnership that will culminate in a white paper on interventions by community-based organizations.

- Dr. Tilly also mentioned other efforts relevant to this subgroup, including a grant to the University of California at Irvine to develop and evaluate an innovative approach to elder abuse prevention, specifically for individuals with dementia. A number of educational efforts are underway, including the HRSA Geriatric Education Center, Administration on Aging (AoA) briefings and webinars about dementia for legal professionals, the Indian Health Service outreach to tribal communities, and the CMS work with a wide variety of Federal agencies and private-sector partners to reduce the use of antipsychotics in nursing homes.

Discussion of Public-Private Partnerships

- Dr. Moulds called for a brief discussion of the public-private partnerships contained in the National Plan and the steps for moving forward with some of them. Each of the three areas covered by the subcommittees entails commitments to public-private partnerships, some of which are underway. For those that are not underway, Dr. Moulds identified a process for moving them forward. He called for recommendations from the non-federal Council members and suggested the appointment of a Federal lead and a non-Federal coordinator.

- There was a discussion of whether a public-private group be identified for each of the three areas covered by the subcommittees or a single overarching public-private partnership group could be formed in each of the areas, and those groups could address public partnership goals or commitments in the national plan and any opportunities that might arise from that dialogue.
- The group decided that, to expedite this work, Advisory Council members will e-mail Dr. Lamont their recommendations for groups or individuals who would be appropriate to include in these conversations.

Overarching Goals and Priorities for 2013

The Advisory Council will offer recommendations for adoption at the January 14-15, 2013 meeting. The subcommittees will bring formalized recommendations to the entire Advisory Council for a vote for adoption. Those recommendations will be issued to the Secretary and to Congress. They will be taken into account as the updated National Plan is written. The timeline for the National Plan will be April and might coincide with the Advisory Council meeting on April 29, 2013. Therefore, the recommendations will inform the update of the plan.

Presentation of Subcommittee Recommendations

The Advisory Council heard the recommendations of the three subcommittees related to the draft National Plan to Address Alzheimer's Disease. Each subcommittee presented specific recommendations, which included sub-recommendations, for discussion.

- ***Long-Term Services and Supports Recommendations*** were presented by Dr. David Hoffman:
  - The subcommittee's primary recommendations and priorities have evolved since the spring meeting.
  - The subcommittee offered 21 recommendations:
    1. States should assure robust, dementia-capable, long-term services and supports systems.
    2. HHS should fund support to a State-lead entity in every State and Territory.
    3. HHS should engage all relevant Federal agencies to include research on long-term services and supports that address dementia capability in their research agendas.
    4. Key information about Alzheimer's disease should be in all curricula.
    5. Adequate training and compensation should be ensured.
    6. Medicare coverage should be redesigned to encourage appropriate diagnosis and care planning for people with Alzheimer's disease and their caregivers.
    7. Long-term services and supports systems should refer people to a health care provider for diagnosis.
    8. Diagnosis should include individual and family in advance care planning (health, legal, estate, and financial).

9. HHS should ensure that systems improve chronic disease treatment for people with Alzheimer's disease.
10. HHS should develop quality measures for the comprehensive care and treatment of individuals with Alzheimer's disease.
11. Practice recommendations for care in every setting should be embedded in surveillance and quality improvement systems.
12. HHS should form a blue ribbon panel of experts to recommend one or more models of palliative care for people with advanced dementia and provide grants through the CMS Center for Medicare and Medicaid Innovation (CMMI) to implement and evaluate the models.
13. Recommendations for end-of-life or palliative care should be part of CMS surveillance and quality improvement systems.
14. HHS should provide grants through CMS CMMI for medical home pilot projects.
15. CMMI should implement a new round of grants targeting preventable emergency department visits, hospitalizations, and lengths of stays (LOSs) for individuals with Alzheimer's disease.
16. HHS and States should partner to ensure access for specific populations, including younger people, people with intellectual disabilities such as Down syndrome, and racial and ethnic minorities who are at increased risk of acquiring Alzheimer's disease.
17. HHS/AoA should use the Federal funds ($10.5 million) for State grants to seed the development of State action plans that maximize use of public and private resources to support dementia-capable long-term services and supports.
18. Funding for the Alzheimer's Disease Supportive Services Program (ADSSP) should be restored to $13.4 million.
19. Caregiver support under AoA should be fully funded.
20. HHS, States, and providers should ensure that caregiver physical health/behavioral health risk is assessed and addressed regularly.
21. HHS should launch a nationwide public awareness campaign to increase awareness and to promote early detection of Alzheimer's disease.

A number of additional issues must be considered, including the timeline for the recommendations; an execution plan and implementation strategy; the possibility of funding the recommendations with existing State and Federal budgets; questions regarding metrics, surveillance systems, and next steps on the State level; monitoring the success of the recommendations; the electronic reporting system; and reporting activities versus progress.

- ***Clinical Care Subcommittee Recommendations*** were presented by Dr. Laurel Coleman of the Clinical Care Subcommittee:
    - Because of the overlap between the Long-Term Services and Supports Subcommittee and the Critical Care Subcommittee, this report augments what has already been presented. The framework for the presentation included workforce, detection and diagnosis, the Affordable Care Act (ACA) and the medical home, multiple chronic conditions, care throughout the stages, advanced dementia, and awareness.
        - Prevention or cure is not imminent. Therefore, robust incentives to work in geriatrics should be offered, including loan forgiveness, and the current workforce

should be "dementia-capable," which requires the development of national standards for certification and licensure.

- Detection tools require education of, and dissemination to, primary care providers. Medicare should provide comprehensive coverage for diagnosis and the care planning visit. Physicians should be reimbursed even if the patient is not present for some of the visit to facilitate planning discussions with family. Enhanced documentation is needed in the medical record, and clarification is needed on the Health Insurance Portability and Accountability Act (HIPAA).
- The current Plan suggests subgroup analysis of existing medical home programs but not new programs. CMMI should consider a specific grant to a medical home for patients with dementia and caregivers, which might be more efficient and effective than including them in a mixed medical home model.
- Alzheimer's disease makes management of chronic diseases more difficult and costly. Very little research exists on best practices or cost-effective management despite the large growth in this population. CMS has not adopted measures in the areas of transitions and rehospitalizations.
- In terms of care throughout the stages, many policy considerations could make significant differences for families dealing with Alzheimer's disease and other dementias.
- Care provided to people with advanced dementia is costly and often burdensome to patients, resulting in poor outcomes. Many areas for improvement align with current CMS initiatives, including management of infections, feeding and nutrition issues, transitional care and hospitalizations, and communication and identification of goals of care. A blue ribbon panel of experts could consider research to identify quality innovations in care delivery or coordination, policy incentives to promote best practices in advanced dementia care in all settings, and the disconnect between Medicare and Medicaid programs for this vulnerable group.
- A campaign for health professionals could emphasize the importance of early detection and skill development in managing people with dementia. An awareness campaign should provide information about where to go for specific needs and highlight the annual Medicare wellness visit.

  - Discussion included the notion of a team approach in the workforce, interprofessional training and education, retraining, system design issues, accreditation standards, patient-centered care, the challenge of care planning, and best practices and public-private partnerships.
  - Other comments centered on the medical home model, licensure and accreditation, implementation, funding and the timeline, and home-based advanced dementia care.

- ***Research Subcommittee Recommendations*** were presented by Dr. Jennifer Manly, Chair of the Research Subcommittee:

  - The subcommittee considered overlap with the national plan and the need for new recommendations to supplement the national Plan.
  - The following four principles drive the subcommittee's work: (1) commit resources with accountability, (2) accelerate basic and translational research toward development of effective treatments, (3) maximize private investment to develop treatments and improve disease monitoring technology, and (4) coordinate in a meaningful manner with global partners.

- The Research Subcommittee report included comments on the following recommendations:
  - *Recommendation 1:* The subcommittee supports and applauds the goal of the national plan to prevent and effectively treat Alzheimer's disease by 2025. Important interim milestones involve significant disease-modifying or substantially enhanced symptom-mitigating behavioral or pharmacologic interventions by 2020. New investment in research must reflect a critical balance between basic research and the urgency of treatment discovery. The implementation plan lacks detail regarding interim goals and explicit timelines for therapy discovery.
  - *Recommendation 2:* Annual Federal research funding must be increased to the level needed to fund a strategic research plan and achieve the breakthroughs required to meet the 2025 goal. Initial estimates of that level are $2 billion per year but may be higher. That investment would be applied to Alzheimer's research initiatives spanning basic, translational, and clinical research. The White House plan for $80 million in new Alzheimer's disease research funding in fiscal year 2013 could represent the initial stages of a ramp-up, but the urgency of getting to $2 billion is unchanged.
  - *Recommendation 3:* This recommendation calls for HHS to develop, execute, and regularly update a strategic research plan and priorities to accelerate breakthroughs in Alzheimer's disease research. However, a comprehensive strategy for applying the recommendations across public and private funding sources has not been developed. The contents of the national plan must be synchronized and coordinated with a research plan, and research should include caregivers.
  - *Recommendation 4:* Clinical research studies, as well as translation of research, should address disparities concerning racial and ethnic groups, socioeconomic status, and populations at high risk for developing Alzheimer's disease, such as individuals with Down Syndrome. Outreach to ethnic groups is mentioned in the national plan (1.B.4), but detailed recommendations regarding leveraging existing resources and engaging private entities are not included, and the National Plan lacks an explicit emphasis on translation of research findings to diverse populations.
  - *Recommendation 5:* The subcommittee recommends accelerating public access to new therapeutic interventions and compressing the timeline, starting with identification of therapeutic targets through regulatory review. Significant overlap exists between the broad intent of the recommendation and the National Plan (1.E.1). Perhaps recommendations 5, 6, 7, and 8 should be consolidated.
  - *Recommendation 6:* This recommendation calls for identifying and prioritizing the action steps needed to reduce the time for moving therapies from target identification and validation through clinical development, regulatory review, market approval, and reimbursement determinations. The national plan should emphasize the role of public-private partnerships in enhancing scientific innovation and discovery as well as progress in shortening the regulatory process.
  - *Recommendation 7:* More detail is needed regarding the recommended actions to be taken by the Secretary to shorten the timeline related to therapy development. The National Plan should include a more detailed description of the steps to be taken to address any identified drug development barriers and to shorten the time from market approval to coverage decision.

- *Recommendation 8:* This recommendation involves the role of the FDA as a partner in the identification of ways in which to shorten the timeline.
- *Recommendation 9:* This recommendation suggests a joint NIH and industry working group to inform research priorities. As public-private partnerships begin, a specific interactive process should be developed for the release of RFIs. The goal is to develop a true partnership between Government and industry to inform research priorities.
- *Recommendation 10:* HHS should develop accurate and relevant metrics for assessing the impact of Alzheimer's disease on the U.S. economy. The next version of the National Plan should make specific references to the economic impact of Alzheimer's disease.
- *Recommendation 11:* This recommendation involves an emphasis on encouraging private investment in the development of treatments. Goal 1.D mentions private partners, but the action items seem to focus on global partners only. This recommendation should be clarified and integrated with other public-private partnership elements.
- *Recommendation 34:* A global Alzheimer's disease action plan, built on international cooperation, would respond to the global scope of the problem. Such a plan should be mentioned in the National Plan, with an emphasis on the coordination of research internationally. Early spring 2013 is the target date for an international meeting. A coordinated international discussion of regulatory hurdles is needed.
- *Recommendation 35:* A specific office and officials within the White House and the Office of the Secretary of HHS should have responsibility and accountability for effective implementation of, and timely and transparent reporting on, all aspects of the implementation of the National Plan. The current National Plan does not mention a separate office in the White House. Other unaddressed areas include details about metrics, milestones, implementation steps, and accountability.

- Dr. Moulds commented on a few points regarding the Research Subcommittee report. HHS convened a series of internal meetings regarding medical product development issues and the Alzheimer's disease pipeline. The conversation included NIH, FDA, CMS, AHRQ, and other entities. Recommendations regarding the structure for private-public collaboration are due in January, but it is unlikely that they can be pulled together by that time. NIH has been involved in the development of the international collaboration action items. Collaboration across governments and several bilateral and multilateral conversations have focused on research, but they have not involved governments as much as hoped. Participants mentioned meetings scheduled to take advantage of the momentum already started.
- Other topics of discussion involved caregiver research, clinical trial infrastructure, a systematic scientific research plan, regulatory pathways, and a national versus a Federal implementation plan. The hope is that as public-private partnerships are convened, private groups will identify the same types of goals and milestones as those cited in the Federal plan.

Public Input

- The Public Comments portion of the meeting was moderated by Dr. Moulds.
- Sixteen members of the public presented testimony, including persons living with Alzheimer's disease, a researcher in disability and human development, family caregivers, the Association for Frontotemporal Degeneration (FTD), CCAL—Advancing Person-Centered Living, Leaders Engaged in Alzheimer's Disease, National Alliance for Caregiving, Alliance for Aging Research, Council on Social Work Education, Alzheimer's Association, and Eldercare Workforce Alliance.
- Speakers made the following recommendations:
    - Recognize the valued voices that people living with Alzheimer's disease can bring to the process of developing the National Plan.
    - Look beyond a one-size-fits-all approach when determining the best way to address the needs of Alzheimer's patients and their caregivers.
    - Recognize the need to eliminate the stigma attached to Alzheimer's disease.
    - Commit to eliminating delayed diagnosis of Alzheimer's disease and to increasing funding for Alzheimer's research.
    - Consider a screening instrument that relates to people with low intelligence (Down Syndrome) and other deficiencies.
    - Consider the entire area of intellectual disabilities and Down Syndrome when updating and revising the National Plan.
    - Look closely at the recommendations of non-Federal members regarding caregivers and include them in the upcoming plan.
    - Recognize the unique challenges and issues related to FTD in the language and actions of the National Plan, with the goal of spreading awareness about the disease.
    - Pay specific attention to the differences between FTD and Alzheimer's disease in curricula for health care providers.
    - Examine the notion of amending the Older Americans Act to ensure access to people with younger onset dementia.
    - Incorporate the notion of person-centered care into the National Plan.
    - Ensure that the international research effort is well coordinated to guarantee efficiencies and expedite solutions.
    - Consider other ways beyond Federal matching funds to incentivize States to invest in Alzheimer's disease and dementia-specific research.
    - Document and articulate the impact of sequestration on the research enterprise and on caregivers.
    - Consider topics such as caregiver assessment, health information technology to support caregivers, family care tax relief, advanced care planning, and increased funding for the National Family Caregiver Support Program.
    - Be very specific in articulating to the Office of Management and Budget the amount of money that is needed for specific programs.
    - Continue to urge expansion of funding and incentives for health care providers to become more knowledgeable about dementia, and encourage individuals to pursue careers in geriatric specialties.

- Lobby for Alzheimer's disease to be at the top of the list of proposed conditions in the Prescription Drug User Fee Act.
- Offer additional recommendations to increase funding to address the quality and quantity of multidisciplinary education and training programs for all primary care physicians and staff.
- Recommend that loan forgiveness be permanent for individuals in geriatrics and gerontology.
- Address the issue of adequate compensation for professional caregivers.
- Advocate for increased Medicare and Medicaid assistance to allow patients with Alzheimer's disease to stay in their homes as long as possible.
- Consult with individuals living with Alzheimer's disease and their caregivers during the process of revising and implementing the National Plan.

Concluding Remarks

- Chair Dr. Ronald Petersen thanked the participants for their moving input and important insights regarding Alzheimer's disease and the national plan.
- The next meeting will take place on January 14-15, 2013.
- The meeting adjourned at 4:17 p.m.
- Minutes were submitted by Dr. Helen Lamont, ASPE.