

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

Washington, DC

April 17, 2012

Advisory Council Members in Attendance

- *Non-Federal Members Present:* Ronald Petersen (Chair), Laurel Coleman, Eric Hall, David Hoffman, Harry Johns, Jennifer Manly, Helen Matheny, David Hyde Pierce, Laura Trejo, George Vradenburg, Geraldine Woolfolk
- *Federal Members Present:* Lynda Anderson (CDC), James Burris (VA), Regina Benjamin (Surgeon General), Richard Hodes (NIH), Russell Katz (FDA), Laura Lawrence (AoA), Shari Ling (CMS), Anna Marsh (SAMHSA), Donald Moulds (ASPE), William Spector (AHRQ), Amber Story (NSF), Brian Unwin (DoD), Joan Weiss (HRSA)
- *Quorum present?* Yes
- *Advisory Council Designated Federal Officer:* Helen Lamont (ASPE)
- *Others Federal Officials Present:* Susan Cooley (VA), Marian Scheinholtz (SAMHSA), Jane Tilly (ASPE), Gilbert Thompson (SAMHSA)

Proceedings

- Meeting was called to order at 9:11 a.m. by Chair Ronald Petersen.
- Introductions of Advisory Council members were made.
- An overview of the agenda was provided and the purpose of the meeting was outlined. The three subcommittees of the Advisory Council (Long-Term Services and Supports, Clinical Care, and Research) have met to discuss the plan and had developed recommendations. The second draft of the National Plan was released on April 13, 2012, but was not reviewed by the full subcommittees. The primary purpose of this meeting was to have the subcommittee chairs report their subcommittee's final recommendations to the full Advisory Council and to vote on whether these recommendations should be sent to the Secretary of Health and Human Services (HHS) and Congress. The approved recommendations will be

sent to the HHS Secretary and Congress as a supplement to the final National Plan.

- Dr. Moulds led a discussion on the development and adoption of voting bylaws for the Advisory Council. Dr. Moulds clarified that the federal members of the Advisory Council would be abstaining from the voting process by choice but that no Advisory Council member is prevented from voting by law. The preamble for the formal Advisory Council recommendations will acknowledge that the recommendations were created in consultation with federal members but that the federal members abstained from voting on the recommendations. The Advisory Council discussed several possible voting procedures. A decision was made that voting would take place after each subcommittee chair reported their subcommittee's final recommendations, followed by an open discussion period by Advisory Council members to request points of clarification and to offer amendments.
- Dr. Moulds made a motion to establish bylaws adopting recommendations by a majority of voting members and will record the vote, including all yeas, nays and abstentions, on all recommendations and memorialize the vote in the recommendations put forth to the Secretary and Congress. As a general rule all votes will be taken as a consent calendar vote with any member having the ability to call for a vote. A second to the motion was offered by Harry Johns. All federal members abstained from the vote. A unanimous vote in favor of was voiced by all voting members.

Presentation and Vote on Subcommittee Recommendations

- The Advisory Council heard the recommendations of three subcommittees of the Advisory Council related to the Draft National Plan to Address Alzheimer's Disease. Each subcommittee presented specific recommendations that included sub-recommendations that were discussed and voted on as part of the recommendations.
- *Clinical Care Recommendations*, presented by Dr. Laurel Coleman, Chair, Clinical Care Subcommittee:
 - The Clinical Care subcommittee reiterated that its goal was to create recommendations that lead individuals with Alzheimer's disease to: (1) have the disease detected and diagnosed at an early stage; (2) receive care planning; and (3) have access to coordinated and high-quality healthcare throughout the course of the disease.
 - The subcommittee offered that the second draft needed additional specificity and needed to be bolder in certain areas.

- Four case studies of patients highlighted the stages of the disease and the varied supports needed by the persons with the disease and their caregivers.
- The subcommittee presented seven formal recommendations:
 1. HHS should launch a nationwide public awareness campaign to increase awareness and to promote early detection of Alzheimer's disease.
 - Advisory Council members discussed the possible addition of a sub-recommendation that included specific metrics for the actions. It was decided that a global comment about the development of metrics for all activities in the plan would be covered in the introduction to the formal Advisory Council recommendations to be sent to the HHS Secretary and Congress.
 - No amendments to the recommendation or sub-recommendations were offered.
 2. Redesign Medicare coverage and physician reimbursement to encourage diagnosis of Alzheimer's disease and to provide care planning to diagnosed individuals and their caregivers.
 - A friendly amendment was offered and accepted to insert new language.
 - The final recommendation is to read: Redesign Medicare coverage and reimbursement for physicians and other health care providers to encourage diagnosis of Alzheimer's disease and to provide care planning to diagnosed individuals and their caregivers.
 3. HHS should develop quality indicators for the care and treatment of individuals with Alzheimer's.
 - Several friendly amendments were offered and accepted.
 - The final recommendation is to read: HHS should develop quality measures and indicators for the comprehensive care and treatment of individuals with Alzheimer's.
 - Sub-recommendation A will read: The Agency for Healthcare Research and Quality (AHRQ)--in consultation with the National Quality Forum (NQF), the Institute of Medicine (IOM), and various stakeholders--should develop quality care measures and indicators for diagnosis, treatment, and care of individuals with Alzheimer's disease.
 - Sub-recommendation B will read: Over time, these quality measures and indicators should cover various settings (e.g., physician's offices, hospitals, home care, nursing home and assisted living facilities, community services); care coordination

- among settings; and transitions between settings, including care coordination during such transitions.
- Sub-recommendation C will read: The Centers for Medicare & Medicaid Services (CMS) should implement demonstration projects to study the application of dementia quality measures and indicators as they are developed.
 - Sub-recommendation D will read: CMS should implement policies for Medicare and Medicaid to embed the quality measures and indicators in the health care system.
4. HHS should provide grants through the Center for Medicare & Medicaid Innovation for medical home pilot projects specifically targeted at improving medical management for individuals with Alzheimer’s disease, including management of co-existing medical conditions and coordination with family and community care providers in all settings (in-home care, long-term care, and inpatient hospital care).
- No amendments to the recommendation or sub-recommendations were offered.
5. HHS should form a blue ribbon panel of experts to recommend one or more models of palliative care for people with advanced dementia, including eligibility criteria and financing mechanisms, and provide grants through the Center for Medicare & Medicaid Innovation to implement and evaluate the models.
- No amendments to the recommendation or sub-recommendations were offered.
6. HHS should create a pilot projects through the Center for Medicare & Medicaid Innovation to implement and evaluate ways to reduce potentially preventable emergency department visits and hospitalizations for individuals with Alzheimer’s disease and other dementias, including emergency department visits and hospitalizations from home, assisted living facilities, and nursing homes.
- A friendly amendment was made to add the term “care coordination” to sub-recommendation A.
 - The new sub-recommendation A will read: Develop a public-private partnership to develop and evaluate ways to improve hospital care, care coordination and transitions of care for people with Alzheimer’s and other dementias, including training approaches and proposed quality measures.

7. Expand funding and incentives for health care providers to become more knowledgeable about dementia and to encourage individuals to pursue careers in geriatric specialties.
 - No amendments to the recommendation or sub-recommendations were offered.
- Dr. Petersen called for additional items for further discussion or changes. No additions or changes were requested.
- Dr. Coleman made a motion for voting members to support the adoption of the recommendations by the Advisory Council as amended. Mr. Hyde Pierce seconded the motion. All federal members abstained from the vote. All voting members voted in favor of the adoption of the recommendations as amended.
- *Long-Term Services and Supports Recommendations*, presented by Mr. David Hoffman, Chair, Long-Term Services and Supports (LTSS) Subcommittee:
 - The LTSS subcommittee echoed the Clinical Care subcommittee's statement that the second draft needed additional specificity and needed to be bolder.
 - In addition, the subcommittee noted that evidence-based strategies are being implemented around the country, but are not being implemented on a scale necessary to meet the need.
 - The subcommittee's recommendations were designed to provide a structure for long-term services and supports to expand in every state and territory so that people with Alzheimer's disease and their caregivers will all have access to the best strategies available today. The members envisioned a broad-based initiative across the Federal Government and not confined to any one particular corner of the Federal Government.
 - The subcommittee presented 15 formal recommendations:
 1. HHS should provide federal funds to support a state lead entity in every state and territory. This entity would coordinate available public and private long-term services and supports, conduct service gap analysis, identify opportunities for efficiency, and enable ongoing stakeholder input to address needs across all sectors and systems.
 - No amendments to the recommendation or sub-recommendations were offered.

2. Recommended use of federal funds (\$10.5 million) currently allocated to AoA.
 - No amendments to the recommendation or sub-recommendations were offered.
3. Funding for the Alzheimer's Disease Supportive Services Program should be restored to the FFY 2003 level of \$13.4 million.
 - No amendments to the recommendation or sub-recommendations were offered.
4. Fully fund caregiver supports under AoA.
 - No amendments to the recommendation or sub-recommendations were offered.
5. Ensure a robust, dementia-capable system of long-term services and supports is available in every state.
 - A friendly amendment was made to sub-recommendation C. The amendment deletes the word "screening" and replaces it with "early detection."
 - The new sub-recommendation C will read: Services for people with Alzheimer's disease include outreach; early detection; diagnostic; care and estate planning; treatment (medical, psychiatric, pharmacological and social/cognitive interventions (e.g., memory classes); care/treatment advocacy (e.g., Medication management, benefits counseling and patient navigation); early stage support services; social support services (e.g., adult day, ADL supports like escorted transportation, meal preparation, home and personal care assistance) supportive housing and home safety assessment/modifications; safety services (e.g., medic-alert, safe return, GPS based programs); and hospital and community-based end-of-life and palliative care.
6. States should ensure that paraprofessional caregivers in every venue are adequately trained and compensated.
 - No amendments to the recommendation or sub-recommendations were offered.
7. Long-term services and supports systems should refer to a health care provider for diagnosis whenever someone is admitted to/assessed for eligibility for long-term services and supports and exhibits signs of cognitive impairment. Providers engaged in diagnosis should consider the 2011 Guidelines for Diagnosis.
 - A friendly amendment was made to sub-recommendation A. The amendment deletes the words ", or has risk factors for Alzheimer's disease."

- The new sub-recommendation A will read: Whenever a person exhibits symptoms of cognitive decline, a diagnosis of Alzheimer's disease should be considered using the 2011 Guidelines.
8. The process of diagnosis should include engaging the individual and family in advance care planning (health, estate, and financial).
 - A friendly amendment was made to the recommendation. The amendment adds the word "legal" to the examples of advanced care planning.
 - The new recommendation will read: The process of diagnosis should include engaging individual and family in advance care planning (health, legal, estate, and financial).
 9. Recommendations for end-of-life/palliative care should be incorporated into all surveillance and quality improvement systems (specifically--CMS).
 - No friendly amendments to the recommendation or sub-recommendations were offered.
 10. Practice recommendations for care in every setting should be embedded in federal and state surveillance and quality improvement systems (specifically--CMS).
 - No amendments to the recommendation or sub-recommendations were offered.
 11. HHS should ensure that health and related systems funded with federal resources should improve chronic disease treatment and related services for people with Alzheimer's disease.
 - No amendments to the recommendation or sub-recommendations were offered.
 12. HHS and state lead entities should ensure that caregiver physical health/ behavioral health risk is assessed and addressed regularly. Caregiver illness and mortality contribute to the enormous personal and financial cost of Alzheimer's disease.
 - No amendments to the recommendation or sub-recommendations were offered.
 13. In partnership, HHS and state lead entities should ensure access to the full array of long-term services and supports for special and emerging populations of people with Alzheimer's disease including younger people, people with developmental disabilities such as Down Syndrome, and others.
 - A friendly amendment was made to the recommendation. The amendment deleted the word "developmental" and adds the word "intellectual" before "disabilities such as Down Syndrome."

- The new recommendation will read: In partnership, HHS and state lead entities should ensure access to the full array of long-term services and supports for special and emerging populations of people with Alzheimer’s disease including younger people, people with intellectual disabilities such as Down Syndrome, and others.
14. State education and health agencies and others should include key information about Alzheimer’s disease in all curricula for any profession or career track affecting long-term services and supports.
 - No amendments to the recommendation or sub-recommendations were offered.
 15. The Office of the National Coordinator, in partnership with the private sector, should ensure that development of health information technology should include tools for caregivers to assist in the care of the person with Alzheimer’s disease to address dementia and multiple chronic conditions and maintain their own mental and physical health.
 - No amendments to the recommendation or sub-recommendations were offered.
- Dr. Petersen called for additional items for further discussion or changes. No additions or changes were requested.
 - Mr. Hoffman made a motion for voting members to support the adoption of the recommendations by the Advisory Council as amended. Ms. Woolfolk seconded the motion. All federal members abstained from the vote. All voting members voted in favor of the adoption of the recommendations as amended.
- *Research Recommendations*, presented by Dr. Jennifer Manly, Chair, Research Subcommittee:
 - The Research subcommittee reiterated that its definition of research includes the whole scope of the research process, including basic research on molecular mechanisms of the disease and the disease process. It encompasses epidemiology using large cohorts, uncovering risk factors for Alzheimer’s disease and possible explanation for disparities in Alzheimer’s disease. The research also includes biological and behavioral markers of Alzheimer’s disease that could be used as end points in trials of potential treatments. Research includes clinical trials of pharmacologic interventions and behavioral lifestyle interventions. In addition, a comprehensive approach to research must take into account development of the research work force.

- The subcommittee presented 13 formal recommendations:
 1. We support and applaud the goal of the National Plan--to prevent and effectively treat Alzheimer's Disease by 2025.
 - No amendments to the recommendation or sub-recommendations were offered.
 2. There is an urgent need for annual federal research funding to be increased to the level needed to fund a strategic research plan and to achieve the breakthroughs required to meet the 2025 goal. Initial estimates of that level are \$2 billion per year but may be more. That investment would be applied to Alzheimer's research initiatives spanning basic, translational, and clinical research.
 - No amendments to the recommendation or sub-recommendations were offered.
 3. We recommend that HHS develop, execute, and regularly update a strategic research plan and priorities to accelerate breakthroughs in Alzheimer's disease research.
 - A friendly amendment added a new sub-recommendation to acknowledge research on caregiving issues.
 - The new sub-recommendation will read: In addition to research on people with the disease, the strategic research plan should also include study of caregivers of people with Alzheimer's disease and the impacts of caregiving.
 4. We recommend that the Administration designate specific offices and officials within the White House and the Office of the Secretary of HHS with responsibility and accountability for effective implementation of, and timely, transparent reporting on, all aspects of the implementation of this National Alzheimer's Plan, including responsibility for issuing statutorily required Reports to Congress on behalf of the Secretary, reports to the Advisory Council, and other reports as warranted.
 - No amendments to the recommendation or sub-recommendations were offered.
 5. We recommend that HHS, in partnership with the research community and industry, take steps to accelerate public access to new therapeutic interventions by compressing the current average time in the process of identification of therapeutic targets, validation of those targets, development of behavioral and pharmacologic interventions, testing of efficacy and safety, and regulatory review.
 - No amendments to the recommendation or sub-recommendations were offered.

6. We recommend that the Secretary, in consultation with academic researchers, not-for-profit Alzheimer's organizations, and the private sector, including sponsors of investigational diagnostic and therapy trials, by year-end 2012 identify and prioritize 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.
 - A friendly amendment added state research coordinators to those the Secretary will consult with to identify and prioritize action steps.
 - The new recommendation will read: We recommend that the Secretary, in consultation with academic researchers, state research coordinators, not-for-profit Alzheimer's organizations, and the private sector, including sponsors of investigational diagnostic and therapy trials, by year-end 2012 identify and prioritize 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.

7. We recommend, as part of the initiative to accelerate public access to new therapeutic interventions, that the Secretary examine and include as part of her annual report to Congress and the Advisory Council how HHS uses existing authorities to reduce drug development barriers and accelerate development of new therapies; immediate steps HHS will take to address any identified drug development barriers, including regulatory hurdles; patent, intellectual property, regulatory science or clinical trial infrastructure weaknesses; and plans to advance regulatory science, guidance, and other initiatives under existing authorities; additional authorities or other legislative action that may be needed to accelerate development of therapies and diagnostics; and immediate steps to shorten time from market approval to coverage decision for innovative therapies and diagnostics.
 - No amendments to the recommendation or sub-recommendations were offered.

8. We recommend that FDA review and periodically report to the Advisory Council.
 - No amendments to the recommendation or sub-recommendations were offered.

9. We recommend that the HHS Secretary develop a continuing process by which research priorities aimed at accelerating the delivery of effective treatments would be set, including input from scientific experts.
 - No amendments to the recommendation or sub-recommendations were offered.
10. To address disparities, we recommend that clinical research studies and activities aimed at translation of research findings into medical practice and to the public include specific targets for outreach to specific populations by racial/ethnic group, sex, and socioeconomic status, and to populations at high risk for Alzheimer's disease (e.g., people with Down Syndrome).
 - No amendments to the recommendation or sub-recommendations were offered.
11. We recommend that HHS develop accurate and relevant metrics for assessing the impact of Alzheimer's disease on the United States economy.
 - A friendly amendment was made to sub-recommendation B that adds the words "as well as the impact on caregivers and worker productivity" to the end of the sub-recommendation.
 - The new sub-recommendation B will read: Identify and rectify the shortcomings of the data needed to assess the prevalence, costs (financial, fiscal and economic), and deaths relevant to Alzheimer's disease, as well as the impact on caregivers and worker productivity.
12. We recommend that HHS commit to an effort to maximize private investment in the development of treatments and improvements in disease monitoring technology by identifying policies that would encourage private industry to invest aggressively in disease-modifying interventions, to support technologies that improve our ability to detect the disease as early as possible, and monitor the disease accurately so that the effectiveness of interventions can be tested.
 - No amendments to the recommendation or sub-recommendations were offered.
13. We recommend that the Administration expand and enhance meaningful coordination with global partners and move forward to establish a Global Alzheimer's Action Plan to respond to the global scope of the problem.
 - No amendments to the recommendation or sub-recommendations were offered.

- Dr. Petersen called for additional items for further discussion or edit. No additions or edits were requested. Dr. Manly made a motion for voting members to support the adoption of the recommendations by the Advisory Council as amended. Mr. Vradenburg seconded the motion. All federal members abstained from the vote. All voting members voted in favor of the adoption of the recommendations as amended.
- Upon adoption of all recommendations, the Advisory Council discussed proposed changes to the *Introduction to Recommendations*. Council members suggested the following edits and changes:
 - Clarify that all references to Alzheimer's disease includes Alzheimer's disease and other dementia.
 - Acknowledge Alzheimer's disease as a public health crisis.
 - Emphasize caregivers and caregiving.
 - Include mention that metrics will be developed to assess the effectiveness of the Advisory Council recommendations.
 - When referencing the healthcare system, include both the health care and long-term services and support systems.
- Dr. Petersen called for any additional discussion or edits. No additions or edits were requested. A motion was made and seconded to approve the *Introduction to Recommendations*, as amended. All federal members abstained from the vote. All voting members voted in favor of adoption of the *Introduction*, as amended.

Plan Dissemination and Next Steps

- Advisory discussion was moderated by Drs. Moulds and Lamont.
- Additional input to the Second National Plan by Advisory Council members moving forward (post meeting) should be submitted to the napa@hhs.gov e-mail address. There is no additional formal comment period.
- The final plan will be released between May 10 and May 14.
- Two personnel changes were announced. Dr. Shari Ling has replaced Dr. Will Shrank as the CMS representative to the Advisory Council. Dr. Jane Tilly is on temporary assignment as the Advisory Council Designated Federal Officer while Dr. Helen Lamont is on maternity leave.
- There is a vacancy on the Advisory Council for a state Public Health representative. The call for nominations is closed and the Secretary of HHS is reviewing applications. The appointee will be named soon.

- The next Advisory Council meeting will be held on July 23, 2012.
 - The agenda will include updates from NIH, AoA, and HRSA on the implementation activities funded in FY2012.
 - Additional potential topics include:
 - Public-private partnerships.
 - Implementation tracking, reporting, and metrics.
 - International coordination.
 - Data collection.
 - Risk adjustment.
 - Novel models of dementia care.
 - Resource mobilization.
 - Dr. Petersen is charged with setting the formal agenda for the next meeting.
- Future Advisory Council meetings will be held in October 2012, January 2013, and April 2013.

Public Input

- *Public Comments*, moderated by Dr. Lamont: Twelve members of the public presented testimony, including persons with younger-onset Alzheimer's disease; a person with Down Syndrome; family caregivers; a health care provider; a reporter; the Alliance for Aging Research; the Alzheimer's Association; the Eldercare Workforce Alliance; Leaders Engaged on Alzheimer's Disease; and the National Task Group on Intellectual Disabilities and Dementia Practices. Speakers made the following suggestions:
 - Include Down Syndrome as a research priority in Goal 1.
 - Include Down Syndrome as a form of early onset Alzheimer's disease, with resources devoted to research, caregiver/family support, and education.
 - Recognize that many parents who are also caregivers of persons with intellectual disabilities who have Alzheimer's disease are "pulling double duty" when dealing with two distinct disabling conditions.
 - Include newly developed instruments for screening for Alzheimer's disease specifically for the persons with intellectual disabilities during the Medicare Annual Wellness Visit.
 - Include awareness of Alzheimer's disease in persons with intellectual disabilities as part of the awareness campaign.

- Acknowledge the needs of caregivers under the age of 18.
- Pay caregivers to provide care and avoid institutional placement.
- Recognize early diagnosis and early advanced planning as key elements for successfully living with the changes associated with Alzheimer's disease.
- Reauthorize the Lifespan Respite Program and increase funding for that program to the authorized amount of \$50 million.
- Provide training for home care and long-term care staff on how to manage persons with Alzheimer's disease who have behavioral disturbances.
- Link reimbursement for services to competencies in providing services to persons with Alzheimer's disease.
- Invest additional funding in the education and training programs under Title VII and Title VIII of the Public Health Service Act.
- Provide additional funding to implement draft plan activities to enhance care quality for the growing number of older adults with Alzheimer's disease and other multiple chronic conditions.
- Include novel incentives/approaches to increase clinical trial participation.
- Establish an interim research-related goal for 2020 or earlier.
- Establish a program that provides a lump sum or cash incentive for finding a cure.
- Find ways to attract and fund new avenues for research.
- Build on the work by the Coalition Against Major Diseases, run by the Critical Path Institute, on strategies for increasing standardization of data for disclosure, pooling, and analysis.
- Name a federal agency to take on lead responsibility for tackling Alzheimer's disease.

Concluding Remarks

- *Concluding Remarks*, provided by Dr. Petersen, Chair:
 - Acknowledged the hard work it has taken to create the soon-to-be published first plan for this country for Alzheimer's disease and noted appreciation for the smooth deliberations around the development of the Advisory Council recommendations.
 - The next Advisory Council meeting will be July 23, 2012.
- Meeting adjourned at 4:00 p.m.

Minutes submitted by Helen Lamont (ASPE).

All presentation handouts are available at <http://aspe.hhs.gov/daltcp/napa/>.