

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

Washington, DC

February 3, 2014

## Advisory Council Members in Attendance

- *Non-Federal Members Present:* Ronald Petersen (Chair), Laurel Coleman (by telephone), Yanira Cruz, David Hoffman, Harry Johns, Jennifer Manly, Helen Matheny, Jennifer Mead, Dennis Moore (by telephone), David Hyde Pierce (by telephone), Amber Story, Laura Trejo (by telephone), George Vradenburg, and Geraldine Woolfolk
- *Federal Members Present:* Dawn Alley (Office of the Surgeon General), Rima Cohen (Office of the Assistant Secretary for Planning and Evaluation [ASPE]), Bruce Finke (Indian Health Service [IHS]), Richard Hodes (National Institutes of Health [NIH]), Ruth Katz (ASPE), Nicholas Kozauer (Food and Drug Administration [FDA]), Shari Ling (Centers for Medicare and Medicaid Services [CMS]), Anand Parekh (Assistant Secretary of Health), William Spector (Agency for Healthcare Research and Quality [AHRQ]), Jane Tilly (Administration for Community Living [ACL]), and Joan Weiss (Health Resources and Services Administration [HRSA])
- *Quorum present?* Yes
- *Advisory Council Designated Federal Officer:* Helen Lamont (ASPE)

## General Proceedings

At 9:08 a.m., Chair Dr. Ronald Petersen called the meeting to order.

Dr. Petersen introduced himself and welcomed meeting participants. Advisory Council members then introduced themselves.

Dr. Peterson commented that at this meeting participants are celebrating an infusion of federal funds and thanked the advocacy groups that pushed for this funding. He said that after the federal subgroups provide updates, the council would hear recommendations for the 2014 National Plan to Address Alzheimer's Disease (National Plan). Public comments would then be received, followed by the council's final discussion of, and voting on, the recommendations for the 2014 National Plan. He

invited Dr. Rima Cohen to address the budgetary changes related to Alzheimer's disease (AD).

Dr. Cohen described her role at the Department of Health and Human Services (HHS), where she is a counselor to the Secretary of HHS, and serves as liaison to the White House. She said that FY 2014 funding for work related to AD was allocated in four specific areas: research, provider outreach and education, fostering dementia capability for home and community-based services, and awareness and outreach.

Dr. Cohen invited council members to provide advice regarding the funding and received the following comments:

- It is important that the allocation of funding be supportive of the milestones that have been set and supportive of the National Plan itself.
- The FY 2014 budget is only a down payment on what is needed for AD, given that the Advisory Council has recommended an allocation of \$2 billion a year for AD research, and recognizing that AD costs the nation over \$200 billion a year. In light of these funding needs, it is hoped that the President's budget for FY 2015 will have higher amounts allocated for AD.
- The Long-Term Services and Supports (LTSS) Subcommittee hopes the President's budget will provide funding support for states to designate a lead entity to organize and direct LTSS, which take place at the state level.
- Participants at the December 2013 G8 Dementia Summit suggested that an amount equivalent to 1% of what a country spends on caring for AD should be allocated to AD research. This 1% figure is a realistic target.

## **Update on Federal Activities**

Dr. Richard Hodes provided an update on milestones for AD research.

- In January 2014, Dr. Hodes, Mr. George Vradenburg, and Mr. Harry Johns reported on the G8 Dementia Summit to the House Foreign Affairs Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations.
- In 2013, the following activities addressed genetics research milestones:
  - A consortium of genetics and genomics experts was established to execute a large-scale sequencing project to identify AD risk and protective gene variants in subjects with late-onset AD.
  - The development of a searchable database identifying regions of the genome that have novel targets was initiated.

- The AD Sequencing Project (ADSP), a large family-based study designed to help identify new pathways for therapy and prevention, is on schedule. In December 2013, ADSP released whole-genome sequence data from 410 individuals in 89 families affected with AD, providing an unprecedented wealth of data to qualified researchers. Future ADSP activities include the following: (1) release of complete whole-genome sequence data in March 2014, (2) release of whole-exome sequence data in the summer of 2014, and (3) issuing a request for applications (RFA) for a U19 cooperative research project in which institutions will acquire and analyze DNA from up to 50,000 subjects.
- Other research milestones completed in 2013 were the development of the International AD Research Portfolio and the convening of the April 30 conference focusing on public-private partnerships, “Enabling Partnerships for Alzheimer’s Disease Drug Development.”
- The following are updates on 2014 milestones:
  - The convening of an advisory meeting to advance rational drug repositioning and combination therapy may be delayed, because the objectives of that meeting might best be accomplished in the broader context of the 2015 AD research summit.
  - Activity has not yet been initiated to establish agreements among stakeholders to expedite rigorous clinical testing of repurposed drugs.
  - A number of awards were granted in 2013 to support the milestone of beginning research to identify and validate six novel therapeutic targets.
  - Multiple studies are in progress related to biomarkers of disease progression, including testing novel PET ligands and novel central spinal fluid and blood biomarkers. Research to develop neuropsychological assessment measures has not yet been initiated. Both national and global efforts are under way to analyze neuroimaging data, through the AD Neuroimaging Initiative (ADNI) and the Biomarkers Consortium.
  - Creating an expert panel of epidemiologists and clinical investigators to recommend how to use existing databases is not planned for 2014.
  - No new dementia cohorts of subjects in midlife have been added to epidemiology studies, but use of imaging markers and cognitive testing is being added to several studies of people in their 50s.
  - The National Institute on Aging (NIA) is very actively planning how the FY 2014 funding will be used to create translational centers to integrate multimodal analysis in preclinical therapy development. A working group is being established to verify standard outcome measures in clinical studies.
  - Increasing recruitment and participation in research studies is in progress through the interagency program Recruiting Older Adults into Research (ROAR).

- Two major research initiatives that will be funded in 2014 are projects to define the function of genes that may cause AD and investigations of the use of optogenetic tools to study the aging of neural systems.
- A report on progress in AD research during 2012–2013 has been issued and is available at <http://www.nia.nih.gov/alzheimer's/progress-report>.
- The Institute of Medicine is convening an expert group to develop a consensus study on the public health dimensions of cognitive aging.

Discussion following Dr. Hodes' presentation included the following comments and clarifications:

- Budget constraints limit research in all areas, from basic science to translation and clinical trials.
- It would be useful to have a funding amount identified for each milestone, as well as a listing of the resources that would be needed to achieve each milestone.
- A planning office tracks and reports on progress toward milestones in an ongoing way, not just annually.
- When studies are funded, such as those funded for FY 2012 and FY 2013, NIA does not know how much money will be available for the out-years of those studies. Consequently, NIA uses a strategy to award only part of an annual budget. Thus, the \$100 million in FY 2014 will be used to fund meritorious applications received in 2013, but new RFAs issued in 2014 will not be funded from the FY 2014 budget.
- There is not enough funding to successfully meet all of the milestones to achieve the National Plan objectives for 2025, but the complexity of research progress makes it difficult to state at what point the funding deficits will make it impossible to meet the 2025 objectives.
- The council needs to monitor the progress in meeting the milestones and make clear statements about deficits that occur. It is hoped that the Administration takes seriously the gap that is occurring. A significant incremental increase in AD research funding is needed in the next budget, just as the budget for AIDS research was increased in significant increments each year.
- Dr. Cohen stated that the council's messages regarding funding were very clear and that she will deliver them to the powers that be.

Dr. Shari Ling provided an update on the activities of CMS.

- In FY 2012, HRSA funded 45 Geriatric Education Centers (GECs), which offered continuing education to 34,000 health care providers in primary care. Partnering with 376 organizations in FY 2013, the GECs provided education to approximately 25,000 individuals.
- Training for providers of AD and related dementia (ADRD) care is being offered for 1 year through Medscape and will be evaluated with pretests and posttests.
- In FY 2014 the budget of \$4 million to train AD providers will be used to develop a unified curriculum, continue professional education offerings, and expand education to lay and family caregivers.
- The National Quality Forum (NQF) is conducting the project “Prioritizing Measure Gaps: AD and Related Disorders,” which will review quality measures and prioritize gaps that exist.
- On February 18, 2014, CMS is holding a listening session on the National Plan, during which stakeholders in the ADRD community can share perspectives on what outcomes should be achieved through health care service delivery.
- The following are activities related to milestones identified in the National Plan:
  - In 2013, the Patient and Family Engagement Campaign (PFEC) was launched through five Medicare Quality Improvement Organization projects focused on dementia care delivery. The final report on PFEC will be issued July 30, 2014.
  - In 2013, six round-1 Health Care Innovation awards focused on dementia were initiated, and applications for round 2 were sought. Evaluation of round 2 will begin in 2014. In 2015, projects will be identified for expansion or scaling.
  - In the project to reduce unnecessary use of antipsychotic drugs in nursing homes, 21 states have surpassed the goal of 15% reduction in use. The range of reduction for all states was from 13% to 21%.

Discussion following Dr. Ling’s presentation included the following comments and clarifications:

- A method should be in place to define appropriate outcomes for dementia care and to measure progress over years. However, it is not possible to measure progress because assessment tools to diagnose dementia are not standardized across health care settings.

- In the United Kingdom (U.K.), which has a closed system of care, it is easier than in the United States to standardize diagnosis tools and to determine progress toward national targets.
- Reaching the goals for clinical care in the National Plan will require establishing immediate, midterm, and long-term goals. Despite many useful activities, progress toward clinical care milestones cannot be measured until people are appropriately diagnosed.
- The council needs to receive a comprehensive update on the new regulations for home and community-based dementia services, including baseline data and plans to evaluate the impact of the new regulations on these services.
- At best, half of people with dementia have been appropriately diagnosed. Although the Medicare annual wellness visit (AWV) is now in place, its implementation is unsatisfactory. Pushing for the implementation of dementia diagnoses as part of the AWV seems to be a fundamentally sound approach to increasing rates of diagnosis. Not having a proper diagnosis of dementia in a patient's hospital chart makes a huge difference in both inpatient and follow-up care.

Dr. Jane Tilly provided an update on the activities of ACL.

- The focus in the coming year in the LTSS arena will be dementia capability for home and community-based services.
- NIA, CDC, and ACL have coordinated efforts to educate the aging services network and strengthen the legal services network.
- The February 2014 issue of *The Gerontologist* was devoted to articles about facilitating culture change in nursing homes to make them "resident centered."
- ASPE will soon release a study that summarizes research on care coordination for people with dementia, focusing on coordinating health and long-term care.
- ASPE recently completed a study of capitated managed LTSS (MLTSS), a growing trend in state Medicaid programs. Twenty-six states are expected to have MLTSS contracts by the end of 2014. Case studies indicated that the transition to MLTSS did not have a disruptive impact on LTSS providers.
- In January, CMS issued a regulation addressing community integration in home and community-based services financed by Medicaid.

Dr. Nina Silverberg of NIA reported on ROAR.

- ROAR uses the CDC, aging services networks, and public health networks to encourage older adults, especially those of diverse ethnic and racial backgrounds, to volunteer for clinical research related to AD.
- ROAR's strategies are to use existing registry platforms, engage trusted messengers from local services and networks, and deliver simple and persuasive messages.
- Thought leaders from public health research, state and Federal Government, volunteer health organizations, and research registries developed a simple call to action: "You CAN make a difference: for yourself and for future generations."
- A draft outreach plan has been disseminated to obtain feedback.

Discussion following Dr. Silverberg's presentation included the following comments and clarifications:

- The primary metric to measure success of the ROAR program is total enrollment in registries.
- Outcome measures should be more refined, because it is common for people to sign up in a registry and never become enrolled in research.
- The Resource Center for Minority Aging Research has been involved in ROAR and will assist in outreach to minorities.
- The Anti-Amyloid Treatment in Asymptomatic Dementia Trial required 20% of people being screened to be from diverse populations.
- The goal for diversity should be for actual enrollment, not just for screening. As an example of lack of diversity, so far in ADNI, 99% of participants are white, well-educated individuals.
- Public health state agencies consider ROAR to be a tremendous step forward, because states have not had enough resources to address AD, and addressing health disparities has been a longstanding challenge.

## **Recommendations for the 2014 National Plan**

### ***Research Subcommittee Recommendations***

Dr. Manly presented the Research Subcommittee recommendations. She noted that the changes from 2013 include reducing the total recommendations from 10 to 6, using

developments from the G8 Dementia Summit to revise the global action plan, and incorporating recommendations emanating from the 2013 ADRD Research Workshop.

- *Recommendation 1:* The interim research milestones first established in 2013 should be evaluated and updated each year to ensure continuing and successful progress toward achievement of this goal.
- *Recommendation 2:* The urgent need to increase annual federal funding to meet the 2025 goal remains a top priority. Actual funding needed may be more than the initial estimate of \$2 billion per year. That investment would be applied to AD research initiatives spanning basic, translational, and clinical research.
- *Recommendation 3:* As recommended in the 2013 ADRD Research Workshop, interim milestones for achieving specific ADRD research goals for the study of ADRD should be explicitly added to the National Plan.
- *Recommendation 4:* HHS, in partnership with experts from the research community and industry, should take steps to accelerate public access to new therapeutic interventions by compressing the current average time taken for the process of identifying therapeutic targets, validating those targets, developing behavioral and pharmacologic interventions, testing efficacy and safety, and regulatory review.
- *Recommendation 5:* The Administration should build on the commitments issued at the 2013 G8 Dementia Summit and take a leadership role in establishing a global AD action plan to respond to the global scope of the AD challenge. This response should include a coordinated international research action plan; a coordinated clinical trial infrastructure for AD, including linked patient registries, longitudinal studies, and trial-ready patient cohorts; a global fund to increase collectively and significantly the funding for AD research; and a policy framework to provide incentives for additional investment in AD research, including improved harmonization of national and regional regulatory regimes regarding AD diagnostic and therapeutic products.
- *Recommendation 6:* The Administration should designate a specific White House office charged with responsibility and accountability for effective implementation of and timely, transparent reporting on, all aspects of the implementation of the National Plan and of the commitments made by HHS at the G8 Dementia Summit, including any global action plan that is developed.

Comments on the Research Subcommittee recommendations included the following:

- Dr. Roderick Corriveau, of NINDS, who was the NIH program lead for the 2013 ADRD Research Workshop, stated that these recommendations to generate milestones for ADRD are doable.

- NINDS agrees with the recommendation for a 2016 summit on ADRD research.
- Establishing a White House office on AD is critical, not only for demonstrating the importance of AD and facilitating global outreach, but also for promoting the establishment of state offices and helping to coordinate state efforts.
- Creating a White House office on AD is not meant to diminish the role of ASPE but to emphasize the transagency involvement with AD.

### ***Clinical Care Subcommittee Recommendations***

Dr. Finke presented the Clinical Care Subcommittee recommendations.

- *Recommendation 1:* Target the dementia awareness campaign toward recognition and diagnosis of cognitive impairment and AD; emphasizing the importance of talking to a health care provider about worsening memory problems; and emphasizing the importance of talking with family members and health care providers about preferences for care.
- *Recommendation 2:* Evaluate the detection of cognitive impairment called for as a component of the Medicare AWW and study possible ways to improve detection and diagnosis of AD.
- *Recommendation 3:* Establish targets and milestones for improving the clinical care for persons with AD and their caregivers through the following patient-centered goals: (a) I was diagnosed in a timely way; (b) I know what I can do to help myself and who else can help me; (c) Those helping to look after me feel well supported; and (d) My wishes for my care are respected.
- *Recommendation 4:* Clarify the privacy protections under the Health Insurance Portability and Accountability Act (HIPAA) to ensure that health care providers can engage in care planning with family members of those diagnosed with AD or other dementias.
- *Recommendation 5:* Evaluate models and demonstrations of payment and care delivery reform regarding the quality of care and cost for the subpopulation of participants with AD.
- *Recommendation 6:* Develop and set targets, strategies, and milestones for ensuring adequate numbers and competence of dementia-capable primary and specialty care health professionals.
- *Recommendation 7:* Increase research funding to improve understanding of advanced dementia.

Comments and clarifications on the Clinical Care Subcommittee recommendations included the following:

- Results of evaluation are unlikely to be able to be reported at the fall 2014 Advisory Council meeting because the evaluation will have just started in 2014, but progress on the activity could be reported.
- Projects outside CMMI, such as care transition, are also applicable to evaluation, so broadening that recommendation beyond CMMI would be a good idea.
- CMS is trying to increase overall rates of AWVs. The AWV requirements call for assessment of cognition but do not specify which assessment tools to use. In addition, there are limits to what CMS can require because of the lack of level 1 scientific evidence regarding cognition assessment.
- Rates of use of the diagnosis code for cognition assessment are low, and it is not clear why physicians do not use the code when submitting Medicare claims. In some cases, they may be doing cognition assessment as part of an Evaluation and Management visit. Having a broader understanding of where care is delivered and what codes are being used for cognition assessment would be helpful in encouraging earlier detection of dementia.
- Cognitive assessment is not a diagnosis but is a required element of the AWV, so billing for an AWV is an indication that a screening was done. CMS may need to expand the specifics of its screening requirements. CMS has great leverage through its reimbursement mechanisms.
- It is known anecdotally that physicians are reluctant to diagnose AD. Knowing all of the reasons for their reluctance would be helpful in developing an awareness campaign.
- The role of the council should be setting actual targets for rates of diagnosis rather than discussing the process. The idea is that establishing targets would cause the process to occur. It is good that the recommendations include a timeline, but targets and milestones are missing from these recommendations.
- Milestones for each recommendation may need to be put in sequence in an organized way, so that the workforce, research, and demonstrations of care delivery, for example, occur in a way that facilitates the overall targets. For instance, it may not be appropriate to prioritize targets for AD diagnosis rates without having education in place for health care providers and caregivers.
- The New York Health Department had very good success in increasing early detection rates. As in many places, providers resisted early detection. In early 2000, the health commissioner sent a “Dear Colleague” letter via email to more than 25,000 physicians regarding the value of early detection. The letter included

references to scientific articles but basically had just four main points. In the following 10-year period, the rates of detection significantly increased.

- Both patients and providers have a resistance to screening that might lead to an AD diagnosis. An increased awareness campaign is needed for the public as well as providers, because many people notice changes in their cognition but attribute it to increasing age.
- U.S. health care delivery is undergoing tumultuous changes right now. This climate is a barrier to progress in detection rates, but we must move forward because of the urgency of AD detection.
- Prioritizing the milestones just postpones progress. We have not made any significant changes in care in the 2 years the council has existed. The Clinical Care Subcommittee drafted these recommendations specifically to focus on barriers to a dementia-capable system of care on multiple fronts. Determining the baseline will be helpful in making improvements.
- Minnesota has gone forward by working with many partners to look at the whole health care system, including detection, diagnosis, support, and hospitalization. This approach might be considered for the entire country.
- The council needs straightforward and candid information from CMS about what goals can be reached and what barriers need to be addressed. For instance, we need to determine whether the AWV can be used as a lever to make progress.
- The slogan “have a check-up from the neck up,” promoted by Patrick Kennedy, is a good message. It doesn’t focus on AD but promotes awareness of many potential conditions, such as stress, depression, FTD, or cognition impairment.
- The work already accomplished through the alzheimer’s.gov website has been valuable, but the website provides the public with information and was not designed to promote awareness. Recommendation 1 focuses specifically on promoting awareness.
- Collaboration between public and private partners is critical, because even though the federal budget allocates \$4.5 million for public awareness, that level of funding is not enough. The Alzheimer’s Association will collaborate and will help with providing resources.

### ***Long-Term Services and Supports Recommendations***

Dr. Hoffman presented the LTSS Subcommittee recommendations. He noted that overlap of recommendations among the three subcommittees is purposeful, and efforts toward meeting goals should not be duplicative but should be integrated when possible. He stated that 33 states now have AD plans, and others are developing them. The

subcommittee continues to support its 2013 recommendation that \$80 million is needed to accomplish the LTSS goals.

- *Recommendation 1:* States should ensure that they have robust, dementia-capable LTSS systems.
- *Recommendation 2:* HHS should provide federal funds to support a state lead entity in every state and territory. This entity will facilitate development of the state's systems, coordinate available public and private LTSS, conduct service-gap analysis, identify opportunities for efficiency, and enable ongoing stakeholder input to address needs across all sectors and systems. HHS should use available funds to begin this process in 2014.
- *Recommendation 3:* HHS should engage all relevant federal agencies to include research on LTSS that addresses dementia capability in their research agendas. Topics needing further research include culturally and linguistically appropriate interventions across settings, and translation of these interventions for persons with dementia and their caregivers; interventions for persons in the early stages of dementia, including interventions that mitigate symptoms of the disease; interventions for persons with Down syndrome and other intellectual disabilities who are at high risk of acquiring dementia as they age; impact of caregiving on health and quality of life of caregivers.
- *Recommendation 4:* State, local, and private-sector organizations should ensure that paraprofessional caregivers in every venue are adequately trained and compensated.
- *Recommendation 5:* CMS should redesign Medicare coverage and reimbursement to physicians and other health care providers to encourage appropriate diagnosis of AD and to provide care planning to diagnosed individuals and their caregivers.
- *Recommendation 6:* LTSS systems should refer people to a health care provider for diagnosis whenever they are admitted to or assessed for eligibility for LTSS and exhibit signs of cognitive impairment.
- *Recommendation 7:* Providers engaged in diagnosis should consider the most current guidelines for diagnosis of AD and rule out and treat any conditions that may mimic this disease.
- *Recommendation 8:* The process of diagnosis should include engaging the individual and his or her family in advance care planning (health, legal, estate, and financial).

- *Recommendation 9:* HHS should ensure that health and related systems funded with federal resources improve chronic disease treatment and related services for people with AD.
- *Recommendation 10:* HHS should continue development of quality measures and indicators for the comprehensive care and treatment of individuals with AD.
- *Recommendation 11:* Recommendations for end-of-life or palliative care should be incorporated into all CMS surveillance and quality improvement systems at the earliest possible time.
- *Recommendation 12:* HHS/CMS activity should include the following:
  - Convene 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; grants to implement and evaluate the models should be provided through CMMI.
  - Provide grants through CMMI for medical-home pilot projects specifically targeted at improving medical and chronic condition management for individuals with AD and coordinating with family and community care providers in the full array of settings.
  - Create a specific grant round of pilot projects through CMMI to implement and evaluate ways to reduce preventable emergency department visits, hospitalizations, and length of hospital stays for individuals with AD; methods should be implemented and evaluated for individuals from the full array of care settings.
  - Convene a panel to recommend innovative means of financing long-term care services and supports.
- *Recommendation 13:* HHS and state lead entities should partner to ensure access to the full array of LTSS for specific populations of people with AD including younger people, nontraditional families, people with intellectual disabilities such as Down syndrome, and racial and ethnic minorities who are at increased risk of acquiring AD.
- *Recommendation 14:* Funding for the AD Supportive Services Program (ADSSP) should be restored to the FY 2003 level of \$13.4 million, and the National Family Caregiver Support Program should be fully funded.
- *Recommendation 15:* HHS, state lead entities, and providers should ensure that caregiver physical and behavioral health risk is assessed and addressed regularly. Caregiver illness and mortality contribute to the enormous personal and financial cost of AD.
- *Recommendation 16:* The Office of the National Coordinator for Health Information Technology, in partnership with the private sector, should work to

ensure development of health information technology tools for caregivers. Tools could assist caregivers by helping to organize care, educating them about dementia and multiple chronic conditions, using home monitoring tools and decision supports, and helping them to maintain their own mental and physical health.

Comments and clarifications on the LTSS recommendations included the following:

- The governor is the right person to establish the state lead agency described in Recommendation 2. The governor manages the executive agencies and can then ensure the coordination of public health services, social services, and behavioral and mental health services, for example.
- Of the 33 states that have published state plans, about 30 have identified a state lead entity in the governor's office. Perhaps the Advisory Council should send its recommendations to governors.
- The recommendations for LTSS need metrics to establish a baseline and measure progress.
- The LTSS Subcommittee considered the inclusion of metrics but was challenged by the fact LTSS are governed by state rules and vary a great deal. Baselines for each state might be established, but having a national baseline is not possible. The only national data set relating to LTSS is Medicare data, and that does not include data on nutrition, housing, legal services, or many other LTSS needed by people with AD.
- Stating patient-centered targets, such as those in clinical care Recommendation 3, might help unify them across different care groups. Then perhaps patient-centered targets could be used across states, even though the care is delivered in different ways. If this is possible, then milestones could be set for achieving these targets.
- If patient-centered targets were developed, there would still be the barrier of collecting information about progress, because there is not currently a way to obtain state information.
- A state lead entity would help in creating more tangible benchmarks. Currently, some support services are provided in the home with no help from community resources, and other services are provided in health care systems.
- Because states have very different ways of implementing LTSS, especially in home and community-based services, measuring how many states are implementing the National Plan recommendations would require a 50-state survey and would be very expensive. Perhaps an easier metric to add is how

many states have a lead agency, starting with the current number of about 30 as the baseline.

## Public Input

Dr. Lamont moderated the public comments portion of the meeting.

Seven members of the public presented testimony either in person or by email, including persons living in the early stages of AD and representatives from the Alliance for Aging Research; the Alzheimer's Foundation of America (AFA); Leaders Engaged in AD; the Association for FTD; the Lucanus Developmental Center of Hollywood, Florida; the National Task Group on Intellectual Disabilities and Dementia Practices (NTG); and Nova Southeastern University College of Osteopathic Medicine of Ft. Lauderdale, Florida.

Speakers made the following recommendations and observations:

- It is critical that the Federal Government and the states partner to help integrate services for people with intellectual disabilities, elder support, and people with dementia.
- Community centers serving residents with intellectual disabilities urgently need the support of programs for AD.
- NTG has almost completed a curriculum for training personnel who work with people with dementia or intellectual disability.
- It is gratifying to see more mention of Down syndrome and people with intellectual disabilities in the recommendations for the 2014 National Plan.
- Increasing efforts to help elderly caregivers who continue to care for individuals with intellectual disabilities would be helpful.
- From the initial National Plan to the proposed plan for 2014, the increase in the focus on metrics and milestones is noticeable and appropriate.
- The Advisory Council should make recommendations for *optimal* research, clinical care, and LTSS, and let the Secretary of HHS or Congress be the party to rein in the recommendations if necessary.
- The increased focus on rates of detection and diagnosis is excellent.
- The efforts to reduce the use of antipsychotic medicines in nursing homes are excellent. A report on state performance in this area should be issued, holding

out as good examples the states that are doing the best, such as Hawaii, and challenging states such as Texas whose performance is poor.

- The following are suggestions to add to or enhance the recommendations for the 2014 National Plan: Establish dementia-friendly communities; reduce isolation; reduce rates of exploitation; reduce depression; reduce impoverishment; reduce levels of pain; foster interstate collaboration rather than having states discuss best practices, because families are mobile, and adult children who share caregiving responsibilities may live in different states and not be able to integrate a parent into community services that are similar from state to state.
- It is critical to make sure the National Plan pertains to changing lives, not putting forward good ideas.
- It would be helpful if the materials for the Advisory Council meeting were issued earlier.
- Amounts of funding needed for completion should be attached to each recommendation in the National Plan. Doing so would help in developing metrics and providing specifics that would give more clout to the advocacy community and families in supporting the plan.
- The cost of the entire National Plan is needed, not just the cost of \$2 billion per year noted for scientific research. The total cost might create “sticker shock,” but that might be a good thing.
- Recruiting older adults for research has been an intractable issue for many years; the ROAR program should expand its stakeholders to include more aging organizations and service groups, such as the membership groups of the Leadership Council of Aging Organizations, the American Geriatric Society, and the American Association for Geriatric Psychiatry.
- The LTSS Recommendation 14 should include lifespan respite.
- The webcasts of the National Advisory Council on Aging meetings are open to the public and provide an excellent way to learn about AD grants being considered and the process and the rationale behind how funding decisions are made. The next webcast is February 26, 2014.
- HHS should immediately conduct an awareness campaign about detection and what to do once someone is diagnosed.
- In health professional curricula, AD is only briefly mentioned and is not integrated into the overall curriculum. Physicians are not educated about the risk of falls and malnutrition or about medication contraindications in AD patients. In many of the

clinical care recommendations, education about AD needs to be enhanced for both professionals and students.

- The community involved with ADRD is very sensitive to language use and was confused by the repeated use of the term AD in the National Plan. Consequently, the National Plan should be careful about the use of terminology.
- The AFA has provided a written request to the White House for funding for age-related cognitive decline and for additional investments in AD research and LTSS in FY 2015.
- A recent Senate resolution calls for doubling funding for AD research in FY 2015 and increasing annual funding to \$2 billion by FY 2019.
- People with early-onset AD should be included in LTSS programs.
- Methods, such as an international web-based portal, must be developed to share program and research ideas and information globally to avoid duplication of efforts.
- A dementia-friendly community successfully developed in Pennsylvania can be used as a model for others.
- Businesses, health providers, local governments, and the public should be encouraged to use people with early-onset AD as resources to help eradicate the stigma of the disease.
- People with AD should have the right to end life in a dignified way.

Dr. Peterson invited discussion about the recommendations proposed by the subcommittees. Council members made the following comments:

- Some consolidation could take place, particularly between the clinical care and LTSS recommendations.
- It is important to remember that in the National Plan the term AD is intended to include related dementias. This is stated at the beginning of the plan itself.
- The LTSS recommendations should include goals and measures and should identify which activities could be done at the federal level and which might be under the jurisdiction of individual states. These additions to the recommendations should be undertaken in the next round of recommendations for the 2015 National Plan.
- Creating a baseline and identifying data sources to measure the activities implemented by states will be a challenge. States do not currently have any

incentive to change how they deliver services, so an investment will need to be made to motivate change. The recommendation to have a state lead entity is critical for coordinating activities and collecting data.

- States are currently looking at ways to reform their Medicaid programs, so now is a favorable time for advocacy groups and thought leaders to suggest changes.
- A timeline is needed for research Recommendation 6, to develop a White House office, and the recommendation should be revised to indicate urgency. It might also be helpful to clarify that the goal of the White House office is to streamline the process of implementing the National Plan, not to add a level of bureaucracy.
- A related recommendation could be that the White House office establishes liaisons with state lead entities. For states without lead entities, the White House office should have the power to incentivize those states to create them.
- The LTSS Recommendation 2 calls for HHS to identify an office to manage funds supporting state lead entities. A bullet or clarification to this recommendation should ensure that this activity is harmonized with the recommendation to create a White House office.
- The global norm forwarded at the G8 Dementia Summit for governments to devote 1% of their care costs to AD is likely to lead to countries' designating officials in their finance or treasury divisions to oversee funding; thus, eventually it may not be appropriate for HHS to have this responsibility, as described in LTSS Recommendation 2.
- When considering the aging population, it is important to go beyond the organizations representing the aging network and address the infrastructures that are in place to serve the aging population.

The non-federal members of the Advisory Council voted unanimously to approve the recommendations and agreed that Dr. Peterson and Dr. Lamont should have authority to make editing changes as discussed.

## **G8 Dementia Summit, December 11, 2013, London**

Dr. Hodes reported on areas of the G8 Dementia Summit that related to research.

- The G8 health and science ministers committed to do the following:
  - Set an ambition to identify a cure, or a disease-modifying therapy, for dementia by 2025.
  - Significantly increase the amount spent on dementia research.

- Increase the number of people involved in clinical trials and studies on dementia.
  - Establish a global envoy for dementia innovation, such as those in HIV/AIDS and climate change.
  - Develop an international action plan for research.
  - Share information and data from dementia research studies across the G8 countries.
  - Encourage open access to data and results from all publicly funded dementia research.
- G8 legacy meetings are planned for 2013 and 2014 to develop cross-sector partnerships and innovation in social impact investment, new care and prevention models, academia-industry partnerships, and research.

Mr. Vradenburg provided the following report related to funding initiatives:

- Governments committed to collectively and individually increase research funding for AD. The U.K. is convening international experts to explore developing a global fund.
- The Global CEO Initiative on AD and the New York Academy of Sciences have begun discussions on alternative funding models, including the following:
  - *Mega fund*: This mechanism is based on the notion that if the justification for investment would lower public cost, then public co-investment can be justified.
  - *Hybrid venture philanthropy*: A fund for start-up companies would have 20% investment from philanthropic sources and 80% from private investors looking for return. Private investors would get 100% of the return.
  - *Crowd sourcing*: A \$100 million fund for start-up companies would be created by obtaining \$5,000 investments from 20,000 investors. Thus, no single investor has a high risk.
  - *Social impact investing*: The concept calls for social investors to buy bonds to fund projects that will reduce costs of a government program. The bonds are subsequently repaid out of government's savings.
- The European Innovative Medicines Initiative is designing a new clinical trial infrastructure in which clinical trial cohorts could be created using registries in which registrants are well characterized through imaging, genotyping, and neuropsychological testing. This approach might reduce both recruitment time and site initiation time by a year.

Mr. Johns gave the following report of the G8 Dementia Summit:

- Even though the G8 Dementia Summit reflects significant global commitment to AD, if the United States does not lead on this, the goal for 2025 will not be met.

For example, the U.K. commitment is to double funding by 2025, but that will not reach the 2025 worldwide goal.

- The Alzheimer's Association, working with AD International, is going to lead a group of similar organizations from across the world in research efforts. Two other initiatives will be addressing LTSS and dementia-friendly communities.
- The tremendous advancements and world efforts ensuing from the G8 Dementia Summit must not distract the Advisory Council from its charge or allow the council to become complacent.

Discussion and comments on the G8 Dementia Summit included the following:

- While the U.K. is taking the lead now, the next steps for the United States are to participate actively in the legacy meetings and promote new global funding models. But U.S. leadership in thought leadership and investment is also critical. U.S. elected officials must not think that global efforts now permit the United States to step back.
- Expanding the shared database of research and increasing its accessibility are extremely important to promote replication when needed to determine accuracy and outcome and also to eliminate duplication when replication is not needed.
- The idea of targeting 1% of total care costs to fund AD has bubbled up from multiple places. It would be helpful to know if that 1% is intended to cover how other countries define AD, and whether it includes ADRD.

## **Food and Drug Administration Update**

Dr. Kozauer presented information about the FDA's activities related to AD drug development.

- AD drug development is a top priority of FDA.
- The FDA's Drug Development Tool (DDT) is a mechanism to facilitate the development of publicly available tools--such as biomarkers, clinical outcome assessments, and animal models--that can be used by any company.
- The Coalition Against Major Diseases has been using DDT to examine biomarkers to enrich clinical trials and is developing a prodromal AD clinical assessment scale.
- In July 2013, the FDA's Critical Path Institute endorsed a Clinical Trial Simulation Tool for use in AD research. Companies can use this tool to model the length and enrollment needed for a clinical trial to have a given effect.

- In February 2013, the FDA published draft guidance for industry titled *Alzheimer's Disease: Developing Drugs for the Treatment of Early Stage Disease*, intended to serve as a springboard for discussion about how to study drugs for populations in the early stages of dementia. The guidance is now being finalized, following a comment period in 2013.
- In the progression of AD, most drug development has addressed the dementia phase. The draft guidance provides a new regulatory framework needed for the development of drugs addressing early AD, defined as symptomatic but predementia.
- The guidance does not endorse any single way of diagnosing patients for early trials. The expectation is that a drug must show benefit in two ways: measure of cognition and measure of function on the global rating scale.
- The FDA has several mechanisms to expedite review of drugs for serious diseases:
  - The Fast Track designation is used for AD drugs and allows companies to have frequent interactions with the FDA throughout the development process; such interaction prevents snags that might delay approval of an effective drug.
  - The Breakthrough Therapy designation has all of the benefits of Fast Track designation and, in addition, the FDA will help a company plan phase 3 trials. For this designation, the therapy must have compelling early clinical data.
  - Accelerated Approval is a process for approving a drug on the basis of a surrogate endpoint that proves to have a clinical benefit. It requires accurate identification of patients. Data do not yet support the use of a biomarker as a single primary outcome measure.

Comments and discussion on the FDA update included the following:

- Because not enough is known about the underlying disease process, the FDA is not in a position to consider a surrogate for approval for AD therapy. It has to be safe and have a clinical benefit in the post-marketing setting.
- If a drug is reasonably likely to be clinically beneficial, a placebo-controlled trial could probably not be ethically justified.
- In correctly identifying patients, it is possible that an instrument to measure cognition might over-identify people with low education or for whom English is a second language. Thus, those people could be incorrectly identified and would not progress to real dementia. Consequently, such instruments need to accommodate diversity.

- With Accelerated Approval, safety is ensured in the same way it is in the regular approval process
- Composite instruments that involve the measurement of both cognition and function are being developed. The FDA guidance will address use of such instruments.

## **Update on the Advanced Dementia Panel**

Dr. Laurel Coleman provided information about the Advanced Dementia Panel.

- The Advanced Dementia Panel comprises 14 members and was created in recognition of the fact that a growing number of people are in the advanced stage of AD and are living with significant disability and significant need for caregiving, at significant cost.
- In the week before the Advisory Council meeting, the panel had its first of three planned meetings, which focused on research and gaps in research. The second meeting, to take place in summer 2014, will address care strategies. The third will take place in fall 2014 and will focus on policy barriers, especially related to hospitalization and skilled care.
- At the recent meeting, researchers gave presentations on family experience, health services utilization, and the state of research infrastructure and funding.
- The Advanced Dementia Panel developed three recommendations to improve the area of advanced dementia. The transcript and slides from the meeting are available now, and an executive summary is being prepared.

Comments on the Advanced Dementia Panel included the following:

- Representatives from numerous federal agencies attended the meeting, and having this interaction was very helpful.
- Discussion on advanced dementia is occurring in other venues as well, such as the Institute of Medicine.
- We need to think of care as treatment. We need to build an evidence base for treatment of advanced dementia. For now, the treatment is in the care.
- The topic of changing the HIPAA regulations to permit caregivers to discuss health care decisions was not discussed at the meeting, but a related topic--people's choices of care as disease progresses--was discussed. The panel agreed that preferences for care should be determined earlier in the disease course.

- The panel focused on defining excellent care for persons with advanced dementia and examining what treatments contribute positively or negatively to such care.
- Care is very diverse, and there are regional differences. For example, the number of transfers between hospital and home or nursing facility varies considerably.
- Research has significant gaps and has very limited funding. For example, the benefits of various decision tools to help the family have not been studied.

## **Brain Health Resources Initiative**

Dr. Tilly reported on the Brain Health Resources initiative, a collaboration between NIA and ACL that also involves the CDC and other institutes and centers at NIH.

- A Brain Health Resource has been developed for professionals in aging and in public health to educate seniors about reducing risk factors associated with brain disease.
- Topics covered in the resource include healthy eating, exercise, sleep, and staying mentally and socially active. The resource, comprising a fact sheet, a PowerPoint presentation, and a handout, will be available soon. Materials are written at a level that seniors can understand. Initially the resource will only be available only in English, but eventually it will be available in other languages.
- During informal pilot testing done in summer 2014, seniors had heard the basic health messages, but a message that was new to them was that keeping one's heart healthy is related to reducing risk to one's brain.

## **Concluding Remarks**

The 2014 National Plan will be issued at the end of April.

The next Advisory Council meeting will take place at the end of April.

The meeting adjourned at 3:51 p.m.

Minutes submitted by Helen Lamont (ASPE).

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