

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

Washington, DC

February 3, 2017

WELCOME

Ronald Petersen, Ph.D., M.D., opened the meeting at 9:01 a.m., thanked everyone for coming, and invited the Advisory Council on Alzheimer's Research, Care, and Services (Council) members to introduce themselves.

PANEL: CLINICAL TRIALS IN ALZHEIMER'S DISEASE AND RELATED DEMENTIAS (ADRD): RECRUITMENT CHALLENGES

Overview

Ronald Petersen, Ph.D., M.D.

Therapeutic drugs are likely to play a major role in reaching Goal 1 of the National Plan to Address Alzheimer's Disease--prevent and effectively treat ADRD by 2025. Developing such drugs requires randomized, controlled trials (RCTs), which in turn requires a lot of participants, takes a long time, are expensive, and are inefficient. Getting adequate participation of consumers and patients contributes to the inefficiency. Panelists will address recruitment challenges and potential solutions.

Food and Drug Administration (FDA) Perspective

Billy Dunn, M.D. (FDA)

FDA defines drugs as products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and intended to affect the structure or any function of the body of man or other animals. Studies address different aspects of drug safety and effectiveness at different stages of research (categorized as preclinical or phase 1, 2, or 3 clinical studies).

FDA approval requires "substantial evidence" of efficacy on the basis of adequate and well-controlled studies. A single study may be sufficient in some cases. Sponsors may seek approval through an accelerated pathway, which allows FDA to consider data based on outcomes other than the target outcome or surrogate markers of effectiveness, which can speed up the development process (but does not increase the speed of FDA approval). These data show the efficacy of the drug on an intermediate clinical endpoint that appears likely to signal a later benefit to the user. The criteria of

substantial evidence applies to both pathways. In some circumstances, FDA works closely with sponsors to streamline the development of products.

Regarding recruitment, FDA engages with sponsors and organizations such as those presenting at this meeting on issues of study design, recruitment, and enrollment criteria to ensure they are aligned with the study goals. By law, FDA assesses the inclusion of underrepresented groups in studies.

Comments and Questions

- **Ronald Petersen:** What constitutes the demarcation between drugs approved by FDA and other products, such as nutraceuticals, overseen by the Federal Trade Commission? **Dr. Dunn:** Drugs are defined by FDA according to their intended use; FDA has jurisdiction over drugs to address disease. Products aimed at normal physiologic processes (such as aging) are a separate area.

National Institute on Aging (NIA) Perspective

Laurie Ryan, Ph.D. (NIA, National Institutes of Health [NIH])

The website ClinicalTrials.gov lists approximately 150 ADRD trials seeking a total of more than 70,000 volunteer participants. Enrolling that many participants requires screening 10 times that number. Numerous challenges to recruitment exist. NIH's Research Implementation Milestones goals include partnering across federal agencies to promote research engagement, funding community partnerships to increase the diversity among participants, and using new technology to reach more potential participants.

To this end, NIH will begin requiring grant applications to demonstrate adequate support and funding for study recruitment. It will also provide an online portal to help investigators plan and implement recruitment. The Agency is fostering targeted outreach by providing tools and information to bridge the gap between clinicians and investigators. It is leveraging digital and other new communication tools to reach more clinicians and the general public. In addition, NIH facilitates discussion at the national level around a shared strategy for recruitment. A new NIH policy requires all investigators to take part in Good Clinical Protocol training, which addresses recruitment and accrual. Starting with funding opportunity announcements (FOAs) in 2018, applicants will have to provide specific information so that NIH can evaluate, for example, recruitment plans and sample size estimates. Beginning in September 2017, NIH-funded investigators will be required to use a single institutional review board (IRB) for multisite studies to speed up recruitment.

In December 2016, NIH convened investigators, private sector funders, foundations, and others to address recruitment, leading to the creation of a steering committee to form a framework for a national strategy for ADRD research recruitment. For this effort, NIA will address issues on the ground at the local and national level. A draft strategy will be presented in the spring for input; the final strategy will be released in July 2017. For

more information, contact Kelley Landy, the new NIA Recruitment Coordinator in the NIA Office of Communications and Public Liaison.

Comments and Questions

- **Ronald Petersen:** Will the NIH incorporate evaluation of the plan for recruitment into grant evaluation? **Dr. Ryan:** Yes; new applications must include specific plans about how trials will be conducted.
- **Ronald Petersen:** Is there a plan to evaluate whether investigators' efforts reach their goals? **Dr. Ryan:** Yes; the science of recruitment should be part of the applicant's trial plan.

Alzheimer's Disease Patient and Caregiver-Powered Research Network (AD-PCPRN)

Rachel Nosheny, Ph.D. (University of California, San Francisco)

The AD-PCPRN seeks to create a network of at-risk people and their caregivers who can be screened and referred for trials. The AD-PCPRN is a subset of the Brain Health Registry (BHR), an online portal for recruitment, engagement, assessment, and longitudinal monitoring for participants and caregivers. Anyone can join the BHR by giving consent, providing some personal information to help identify suitability for research protocols, and completing three online cognitive tests to help with the assessment. A registrant can invite a study partner, such as a caregiver or family member, to join.

More than 30,000 people, all 55 years of age or older, are enrolled in the AD-PCPRN. Of the nearly 13,000 for which there are data, about 64% provide enough information to assess eligibility for trials. The registry has a good age distribution but is predominantly female, White, and well educated, which does not reflect the demographics of the country or the burden of Alzheimer's disease in communities.

Prescreening finds about 69% of registrants are ineligible for studies. Of the 10,000 users referred to Alzheimer's and aging clinical studies (including observational studies), 757 have been enrolled. Several steps are being taken to improve enrollment:

- Facilitating direct referral to studies that does not require consent to join the registry.
- Adding a portal for investigators to give more feedback about referred candidates.
- Collecting user data to improve algorithms that identify risk.
- Increasing education about participating in studies.

The BHR has enrolled about 1,900 study partners who can give insights into participants' function and diagnoses. Partners' health information will be used to improve caregivers' health.

Comments and Questions

- **Marianne Shaughnessy:** What happens to users who are deemed eligible but do not live near a trial site? Does the BHR provide other resources or keep track of them? **Dr. Nosheny:** The BHR engages users over time with newsletters and education to keep them in the pool in case they become eligible for future trials. The BHR has 52,000 registrants of all ages; the AD-PCPRN is limited to people over 55.

Banner Alzheimer's Institute Alzheimer's Prevention Registry and GeneMatch Program

Jessica Langbaum, Ph.D. (Banner Health)

Registries can identify and screen a pool of potential candidates and also complement local and grassroots recruitment efforts. Challenges to setting up registries include motivating healthy people to join, managing the logistics and legalities of collecting and sharing data, implementing advanced technology and a high level of customer service, and ensuring adequate funding. The Alzheimer's Prevention Registry allows anyone age 18 or older to sign up, anywhere in the world. Registrants provide minimal contact information and receive emails with education and research opportunities. About 260,000 people, mostly women, have signed up since the site opened in 2012.

The registry is linked to GeneMatch, which is open to United States residents ages 55-75 years old. GeneMatch participants complete an online education module and a self-administered DNA test. Results are used to identify potential candidates for trials. Results are not sent to the participants who submitted their DNA, which is the most common reason given for not taking part in the GeneMatch registry. Partner sites--physical locations where registered users can pick up a DNA test kit--require approval from a central IRB (a barrier for institutions unwilling to relinquish local control). About 31,000 people, mostly women, are enrolled in GeneMatch. Of those, 264 have been invited to participate in the Alzheimer Prevention Initiative's Generation Study; 123 have accepted.

An example of a successful and cost-effective outreach effort is GeneMatch's use of Facebook advertising, which brought in 16,000 new members. To increase representation of underrepresented minorities, outreach must use clearer, more accessible language and translate materials into Spanish. There should also be efforts to develop a repository of participants who failed screening so they can be contacted about potential inclusion in future studies. A national IRB for registries would be useful. Additional funding is needed to enhance the effectiveness of registries.

Comments and Questions

- **Ronald Petersen:** Is IRB approval required for enrollment? **Dr. Langbaum:** The Alzheimer's Prevention Registry is a mailing list, so it does not require consent or IRB approval. GeneMatch requires individual consent.
- **Sowande Tichawonna:** Does the Banner Alzheimer's Institute have people of color on staff? **Dr. Langbaum:** No, but we are seeking to hire an outreach coordinator for Hispanic communities. We have a family and community services department that has two people of color who help us with outreach, but they do not directly report to me on the registry team.

Global Alzheimer's Platform (GAP)

George Vradenburg (UsAgainstAlzheimer's)

The GAP aims to speed up Alzheimer's clinical research through several mechanisms, including increasing the volume and efficiency of recruitment. It aims to create a high-performing network of certified trial sites using a national IRB and standardized processes, contracts, and training. With scientists suggesting the need to study Alzheimer's disease earlier in its development (e.g., in cognitively normal people), the current research delays will translate into even longer study timelines. Engaging communities through multiple avenues is effective in overcoming barriers. Establishing clear minority recruitment goals and minority-friendly referral programs is vital to ensure that study results are generalizable. Better engagement with health systems and primary care providers (PCPs) is needed. Performance must be measured through metrics that can help organizations innovate and improve.

Partnering with the BHR, the GAP tested social media recruitment in several markets, collected cost data, and assessed barriers to using registries. The GAP is planning an open-source, interoperable database that can be used across systems. The economics of recruitment are challenging and require a cost-effective, innovative approach. The GAP provided \$100,000 to 11 pilot sites in the GAP-Net network to invest in areas that grant funding rarely allows, such as hiring recruitment coordinators, which increased enrollment by nearly 43%. The network now has 45 United States and Canadian sites, all of which must meet quality and performance metrics informed by the pilot site results.

In Kansas City, Missouri, the GAP is engaging local government, businesses, health systems and PCPs, minority-serving institutions, faith-based organizations (FBOs), and philanthropic resources to identify and break down barriers to recruitment. For example, we informed health care systems and PCPs that trial sponsors will cover the cost of a neurological workup to identify potential participants, so neither patients nor Medicare have to pay for that step in the recruitment process. Providing the mayor with data about the number of citizens with AD/DRD helped make the case for increasing recruitment.

The Council should consider not just how to increase participation, but also how to distribute participants across the spectrum of disease stages. The study population must include more minorities. The research enterprise should become more customer-friendly and work to keep potential candidates engaged, combining digital media and local efforts. Study sites must increase capacity to process candidates at the local level. Investigators must continuously measure what works, make adjustments, and evaluate costs. At the federal level, interagency collaboration can help on numerous fronts related to recruitment.

Comments and Questions

- **Myriam Marquez:** Efforts should focus on senior community centers, especially to reach minorities. **Mr. Vradenburg:** When there is a person at the community center focused on the issue, they do reach people. Also, leveraging the reach of FBOs is powerful. We need to address other barriers, such as housing discrimination and transportation problems. We also need to build trust among minorities to overcome the history of mistreatment and the sense that academics only pay attention to minority communities when they want something.
- **Laura Gitlin:** The aging networks--senior centers, adult day care services, meal delivery services, and the like--are a prime source for aggressive recruitment. They are trusted in their communities and serve diverse groups, including low-income people, who are also underrepresented in studies. **Mr. Vradenburg:** The GAP is testing that concept in Kansas City, Missouri.
- **Mary Worstell:** Other resources include the U.S. Department of Health and Human Services' (HHS's) Partnership Center, which has broadened its initial focus on outreach to FBOs to include providing guidance and leveraging the influence of faith leaders. The U.S. Department of Transportation invested \$1.9 million in 19 communities for its Rides to Wellness program to increase access to health care services, and another round of those grants will be announced in March. The HHS Office of Minority Health should be engaged; it is beginning to invest more in older people. **Mr. Vradenburg:** These are great suggestions. In Kansas City, Missouri, the GAP is talking with the ride-sharing company Lyft about how to resolve some transportation barriers.

Alzheimer's Association TrialMatch

Keith Fargo, Ph.D. (Alzheimer's Association)

Launched in 2010, TrialMatch links people interested in participating in research to a database of clinical trials and other studies across the spectrum from healthy individuals to those with endstage dementia. Users create an account and complete a profile online or by phone that includes self-reported health status. The profile is assessed against a database of more than 275 trials to create a customized list of trials for which the user would be a potential candidate. Users determine which trials may be of interest and click through for more information.

TrialMatch works on computers and mobile devices (minority communities are more likely to use mobile devices to get online). Various features aim to provide a user-friendly experience. Users can read clinical trial summaries in lay language or review the descriptions provided in ClinicalTrials.gov. Notably, when a new trial is added to the database, TrialMatch's second-pass mechanism automatically reviews profiles of users and emails those who may be eligible for the new study. The study database comes from ClinicalTrials.gov and from researchers who provide details (including proof of IRB approval) about studies not listed in ClinicalTrials.gov.

TrialMatch reaches out to potential users through promotional videos and self-mailers distributed at sponsored events around the country. In 2016, 56,000 new TrialMatch accounts were created. About 40% of those completed profiles. Of those, approximately 15,000 clicked through to review a study summary. Second-pass matching, which ramped up in the second half of 2016, reached 40,000 people and had a very high click-through rate (37%).

Future challenges for TrialMatch include matching younger, healthier people to studies on early signs of disease and increasing diversity to better understand and reflect the burden of disease. To reach underserved minorities, The Alzheimer's Association is boosting Spanish-language promotion of TrialMatch. In 2016, the percentage number of racially and ethnically diverse users grew more than overall users.

Comments and Questions

- **Ronald Petersen:** Is IRB approval required for TrialMatch? **Dr. Fargo:** TrialMatch does not involve human subjects research, just data collection and matching, so IRB approval is not required.
- **Laura Gitlin:** Is TrialMatch open to any kind of clinical trial? **Dr. Fargo:** Yes, including trials focused on caregivers. TrialMatch has ramped up outreach to the scientific community to encourage more investigators to list their trials in its database.
- **Sowande Tichawonna:** Are there databases of African American or other minority patients with a history of Alzheimer's disease that could be linked to TrialMatch? The Alzheimer's Association's promotional video would be effective in minority communities. **Dr. Fargo:** The Alzheimer's Association has relationships with some key organizations to disseminate the video and messages about clinical trials to more minorities.

Discussion

- **Myriam Marquez:** Are there studies taking place in Colombia, which has a huge Alzheimer's referral network? **Dr. Langbaum:** Banner Institute is a cosponsor of a trial in Colombia; we funded a registry of kin that identified over 5,000 living

members, and that continues to grow. It is a tremendous resource to the scientific community. The registry provides an observational cohort, where people come in for memory and thinking evaluation.

- **Mary Worstell:** How does an interested individual find out about registries? Is there a central source? Does the multitude of registries cause confusion or dilute the pool of potential participants? **Dr. Fargo:** The Alzheimer's Association envisions TrialMatch as a gateway; it includes links to the BHR, GeneMatch, and others. Having multiple ways into the system may be a good thing. **Dr. Nosheny:** All the registries are working together and doing cross-promotions. However, it may be appropriate to consider streamlining to help individuals understand the various options. **Dr. Langbaum:** Registries are just beginning to learn what works; it is likely that one size will not fit all. **Dr. Ryan:** NIA offers the Alzheimer's Referral Center in English and Spanish. **Mr. Vradenburg:** The target should be developing a common measure of performance of recruitment efforts--specifically, the cost per individual enrolled in a randomized study per month--and improving performance.
- **Mary Worstell:** Federal products, such as new education modules for PCPs and caregivers, could include information about the registries and links to them. **Mr. Vradenburg:** A certification program that covers geriatrics could be developed to educate PCPs and perhaps act as an incentive if providers received additional reimbursement for implementing the teachings. **Dr. Weiss:** The Health Resources and Services Administration (HRSA) is working with the Centers for Disease Control and Prevention (CDC) on educational modules that qualify for continuing education credits for doctors and nurses; a module could be developed on patient recruitment. Registries should reach out to HRSA's community health centers and federally qualified health centers, which serve a lot of underrepresented and minority communities, as well as the National Association of Community Health Centers.
- **Joan Weiss:** Registries should seek opportunities to link to the neurological disease trials supported by the 21st Century Cures Act. Which registries address dementia that is not related to Alzheimer's? **Dr. Nosheny:** The BHR does not target Alzheimer's exclusively, but referrals are currently limited to Alzheimer's trials. **Dr. Langbaum:** The Banner Institute is focused on Alzheimer's prevention; it also promotes studies of asymptomatic adults. Notably, the Institute provided the infrastructure of the Alzheimer's Prevention Registry to another group that is developing a frontotemporal degeneration (FTD) disorders registry. **Mr. Vradenburg:** The GAP feeds into whatever trials are being done in a given community. All the feeder systems address dementia but are not Alzheimer's-specific.
- **Deborah Olster:** What is unique about ADRD in relation to study recruitment? **Mr. Vradenburg:** It is difficult to recruit healthy, cognitively normal people into trials. Studies of mild-to-moderate Alzheimer's disease tend to recruit quickly

from a pool of diagnosed patients. **Dr. Petersen:** People with symptoms may not be aware they have the disease. **Harry Johns:** Only about half of families and one-third of individuals know or are told they have Alzheimer's disease. **Dr. Fargo:** Most studies must recruit both the affected patient plus a study partner (caregiver or family member) to report on cognition and function.

- **Shari Ling:** The Centers for Medicare & Medicaid Services (CMS) has new billing codes to facilitate payment for cognitive assessment and caregiver assessment. The health care system is transforming to deliver better outcomes over time, so opportunities are evolving. Clinicians may need clear signals about who is eligible for trials; some CMS opportunities are targeting practice improvement to help busy providers looking at numerous aspects of patient care. In the Medicare population, patients with Alzheimer's disease are likely to have concurrent conditions that may affect the trajectory of the disease. Often, patients with cognitive problems are not diagnosed. Also, uptake of diagnostic tests and coverage decisions both require demonstration of clinical utility as well as validity, which can be especially challenging with comorbidities.
- **Rachel Nosheny:** Consider the potential of the BHR model to act as a new cognitive health screening system for routine care and to aid in diagnosis.
- **George Vradenburg:** We should work with CMS to measure the costs of recruitment and encourage PCPs (e.g., with compensation) to counsel and refer patients.
- **Marianne Shaughnessy:** Do the registries collect data on the user experience to learn why registrants do not enroll in studies? **Dr. Fargo:** TrialMatch can track what links users follow and how long they stay engaged. **Dr. Langbaum:** The Alzheimer's Prevention Registry and GeneMatch collect a lot of feedback; monthly usability testing is conducted. We also use analytics to track what users click on. **Dr. Nosheny:** Participant feedback shapes the questions and site options.
- **Joan Weiss:** Registries should reach out to officials at the U.S. Department of Housing and Urban Development who oversee housing for seniors. There is significant interest in the field in collaborating with federal agencies. **Mr. Vradenburg:** Non-federal organizations need to figure out how to work together and understand the mechanisms that different federal agencies control. **Donna Walberg:** Thanks to work by the Administration for Community Living (ACL), some States are emphasizing the importance of building relationships with clinicians and systems to address issues around aging generally, so there is a national organization that can assist with integration. State-level systems can have immediate impact (e.g., through outreach to cultural consultants who can spread the word about recruitment in diverse communities).

- **Ronald Petersen:** A fundamental challenge to developing a metric is the fact that registries do not require trials to report back about the outcome of referrals. **Dr. Nosheny:** The BHR has a mechanism for reporting back but it is voluntary. The science of recruitment is emerging; it is not yet known what variables are associated with successful enrollment. **Dr. Langbaum:** GeneMatch relies on researchers to report. We are considering creating a contract that requires feedback in exchange for promoting a study. **Dr. Fargo:** Measuring outcomes data is also hampered by privacy issues. Another organization tried to require study sites to report back as a condition of inclusion in its registry. However, faced with enforcing the condition (and thus limiting recruitment for a trial), the organization chose to continue promoting the study. Ideally, a collective effort could be made to develop a tracking mechanism. One option may be to ask centers for Alzheimer's disease research to track where users come from. **Mr. Vradenburg:** The GAP requires feedback as a condition of participation. The new NIH Alzheimer's Clinical Trials Network should collect data. Establishing standard performance metrics and reporting requirements across networks as we build capacity would help with tracking. **Dr. Ryan:** Recruitment and innovation are central to new networks, so NIH will look at metrics.
- **Richard Hodes:** Successful recruitment involves engaging consumers at multiple points, but not all of the players are used to customer service. Metrics should be paired with incentives. Sometimes, national requirements can act as a disincentive. NIH and NIA can enforce better data collection and provide leverage to increase reporting at the top and the bottom of the funnel.
- **Helen Matheny:** Do all of the registries provide educational information? If so, does that information target the general public or PCPs? **Dr. Nosheny:** The BHR provides education through its newsletters but would like to give users customized information they can act on. Most of the outreach is aimed at the general public, but with some studies, the BHR communicates with the in-clinic cohort. **Dr. Langbaum:** Most of our outreach aims at the general public. Efforts to work with PCPs and their networks have not been very fruitful because PCPs feel overwhelmed, and research is not a priority. **Dr. Fargo:** We provide a lot of tools to PCPs (e.g., a prescription pad with a link to TrialMatch, a pocket card application for physicians). There is a tremendous opportunity with care planning sessions to educate physicians about encouraging patients to enroll in clinical trials. TrialMatch is embedded in the Alzheimer's Association website, so users have access to all of the association's information. **Mr. Vradenburg:** The GAP will work in every segment of a local community where people get information. **Ms. Matheny:** Registries should consider working with Dementia Friendly America.
- **Mary Worstell:** Recruitment seems to offer a secondary opportunity to reach caregivers and refer them to resources, such as modules in development by the Office on Women's Health and HRSA about maintaining well-being while

providing care. **Dr. Nosheny:** The BHR would like to give back to caregivers, perhaps with an online intervention.

- **George Vradenburg:** We should look closer at how the NIH's Precision Medicine Initiative, which aims to recruit one million volunteers for research, could contribute to ADRD research recruitment efforts. **Dr. Ryan:** The trans-NIH initiative has been renamed All of Us.
- **Ronald Petersen:** To have an impact on public health, we need to engage more asymptomatic people. Measuring therapeutic effects in such people probably requires the use of biomarkers. Where does FDA stand on biomarkers as an endpoint? **Dr. Dunn:** A sponsor using a biomarker as an endpoint would pursue the accelerated pathway for approval. Such approval would require the product sponsor to confirm the effectiveness of the drug later on, which is difficult but possible. Ideally, a biomarker acts as a true surrogate that does not just enhance prediction but reliably indicates what will happen years later. More patients are needed in RCTs so that Alzheimer's disease can be better understood and drug developers are not shooting blindly at a target. Better understanding will enhance knowledge about useful biomarkers.

PUBLIC INPUT

Public comments are transcribed below verbatim.

Michael Ellenbogen (submitted in writing)

I am making a formal request that the NAPA committee takes this issue to the top level of the HHS management as I believe what you are doing is not complying with the law. On Friday, January 6, 2017, 1:07 p.m., I sent an email for the February 3 meeting attendance as you can see below. I was denied this access, and I am not being treated fairly under the disability guidelines. For 2 years now, I have been ignored, and so many others with dementia are not being heard. This must change. The email reads: "I am requesting to speak at the next meeting public comments for the February 3 for NAPA. I am specifically requesting: reasonable accommodation under section 504 of ADA (Americans with Disability Act) to present my portion of the speech presentation by computer-link with video, or a telephone link-up such as conference call."

William Mansbach, CEO of Mansbach Health Tools and CounterPoint Health Services (submitted in writing)

Many of you on the Council are familiar with our BCAT--Brief Cognitive Assessment Tools. I am honored to sit on the Maryland Governor's Alzheimer's Disease Council. I ask this Council to include scientifically validated brain health programs as part of its comprehensive recommendations. Our new ENRICH[®] program is one example. There are four "steps" to ENRICH: (1) an explanation of the six brain-healthy habits to mitigate your risk for dementia; (2) the free ENRICH[®] Calculator, which measures how well you currently are managing these habits; (3) the opportunity to take a cognitive self-

assessment or schedule a “virtual” BCAT cognitive assessment; and (4) suggested “next steps.” We developed this program to address the needs of family caregivers, adult children of those with dementia, and others who are concerned about their risk for developing dementia. Modifying risk factors, increasing brain health, and screening are important factors in early detection and perhaps in delaying the onset of cognitive impairment. We’d be happy to assist the Council in developing programs to promote brain health, to screen for cognitive impairment, and to provide nonpharmacological interventions for those who are cognitively impaired. For more information, please visit our new website, <http://www.enrichvisits.com>.

Tom Buckley

Hello. Three points I’d like to make if I can today. First, I’d like to thank again your Committee and Erin Long for funding dementia care coordinators. I have my son with us today. And Benjamin Wiley, for the first time in Florida, have specialized coordinators that went into every home of every family with Alzheimer’s disease and aging persons. With their visits, they found moms--one mom was a diabetic, one leg, only spoke Spanish, her daughter came once a month. Nobody had ever talked to her with a support plan or creating a plan. Now, it’s so simple to write back and forth in Spanish. They created 20 assessments, person-centered dementia care plan, caregiver groups, and Florida will permanently fund them, recognizing that value. Truly meet their needs.

Secondly, on Monday we’ll start our first--which is incredible--it will be our medical home with Nova College of Medicine, Broward Health. We are going to eliminate this health care disparity with the intellectually disabled. For 7 months I’ve been sitting in a bedroom, gained 28 pounds, studying every single death. CMS has written great documents to guide us and lead us but we know now it’s going to take training the medical staff. We have audiology, dentistry nodding their heads yes; Nova has given two colleges to eliminate the disparity and teach every single dentist, audiology, legal--and it’s just unbelievable. Zero psych.

But when you see people with disabilities--I adopted a little girl, 22 years of age, she was in my class for family disabled, and they said she would die in 3 months. I said, we can’t have it happen. The family said, well, we’re not going to spend the money, the hospital won’t spend it either. They said you adopt her at Philadelphia orphans court, she’s yours. I adopted her. Three weeks ago, my son and I were in New York. And they called me from the hospital and said we’re going to start hospice on her. I said, what happened? They said, she just lays there. I go, no, she’s non-verbal. She’s 65 pounds, scared to death. She won’t move. So they called us three more times. I finally said I’m going to come over.

I’m ready to deal with it. I went over there. As soon as I turned the corner, she screeched and yelled and jumped out of that bed and grabbed me. And didn’t let go. She was fine. Nancy was who she always was for her whole life. Two minutes later the lady goes, see, she has no quality of life. To you she has no quality of life. She is my life. You don’t get to decide the value of Nancy to me.

I thank you for everything you do. We're going to reach out to those poor and with unmet needs until they are met. Thank you.

Mary Hogan

I'm glad to be back. I know there's some familiar faces and some unfamiliar faces. So I'm just going to briefly tell you a little bit about what got me here. I've been coming for the last 5 years. I'm dedicated to issues related to people with intellectual disabilities, specifically Down syndrome. I did homework before coming today in regards to the issues related to clinical trials, and I know that Dr. Hodes this afternoon in his agenda will address biomarkers. The participation of people with intellectual disabilities in clinical trials is difficult because of issues around capacity and consent, but I do hope we continue to provide opportunities for people. There's another study going on right now with NIA and LA MIND, I think it is, and a pharmaceutical company about the use of a monthly injection around medication, so I think this is a community that should be considered for inclusion. Had I had this opportunity when my brother was a young man, long before the onset of disease, I would have considered participation in a clinical trial for him if I had realized where we were headed. And what I sent to Rohini [Khillan]-- there was an attachment from the NIH, it's called "Researcher's Seek Alzheimer's Clues in People with Down Syndrome," it's a simply put-together document that's informative for those on the panel not fully informed about issues related to people with intellectual disabilities, most specifically Down syndrome. And the other thing I did submit to you is a small list of issues that we still continue--that continue to persist for us. I won't go over that, but it's in your handout.

In a nutshell, we still have lots of challenges around diagnoses, misdiagnoses, and missed diagnoses--one of our biggest challenges. We have people in their early 20s diagnosed with dementia, people with Down syndrome being diagnosed, so obviously there is misunderstanding in the medical community about the incidence and what comorbid conditions can impact the person and mimic dementia. And we have other conditions that need to be studied to better understand decompensation in young adults with Down syndrome.

The other thing is the workforce issue which I brought up last month in follow-up to last July's meeting, and I think there continues to be some major issues around preparing our workforce so that they are better able to manage and support families and individuals as they age. We come to you as the NTG [National Task Group on Intellectual Disabilities and Dementia Practices], a nebulous thing. It's about 120-150 people, grassroots operation; we're doctors, we are clinicians, we are psychologists, we are family members, we are dietitians, we are a whole lot of different things but what we have most is heart, and I think that we're really committed to this population, and I think I feel like I always come and ask you to do something, and I guess I'm here briefly to say that you in turn need to know the kind of things we're doing.

We have this early dementia screening tool used widely that's been translated into a number of languages. We're just participating with the National Down Syndrome

Society, and Alzheimer's Association is reviewing the revised edition for an upcoming publication on Down syndrome and Alzheimer's disease, a public-private sort of partnership there. And recently we began an online support group, and we were really assisted in this effort by the National Down Syndrome Society and CurePSP, who gave us the model in terms of doing a peer support group, and this is a growing effort from the National Down Syndrome Society in terms of supporting families around the country. So we're doing something to help you, and we look to you to continue to help us and to know that we're out there and we're not probably going to go away. And we have a real commitment to this group of people, and I mean it personally, I'm here to say that I support what's happened very much in the last 6 years. I think we've made great progress, and if we continue to have this kind of dialogue I'm hopeful that we'll continue to be able to improve the lives of people with intellectual disabilities and Down syndrome and family caregivers who are very devoted to one another across the lifetime. So thank you very much.

Matthew Janicki

I'm Matt Janicki, with my colleague Seth Keller, we are the co-chairs of the NTG. You've heard me speak. Seth has been here as well. I wanted to--I had prepared remarks in your document, but I wanted to echo what Mary just said. I was thinking back, a couple minutes that she had to talk to you, about what has stimulated us as a National Task Group to try to accomplish a lot of things in the United States and even outside the United States in terms of furthering and bettering lives of people with intellectual disabilities, aging, and who are affected by neuropathologies. A lot is attributed to what you're doing. The National Alzheimer's Project Act and the Council stimulated us to be there as a complement to what you're doing with the general population and what we're trying do with this segment of the population. And I wanted to talk about one thing.

One of the things we've been trying to do is--Mary outlined--providing materials around people with intellectual disabilities and nuances in terms of dementia and what people are doing in terms of providing services. We had joined with some colleagues in Scotland last October and held a summit, kind of going along with what everybody else was doing in terms of a summit on intellectual disabilities and dementia. We had people from 15 countries come [from] Europe, North America, and people involved in this area --academicians, researchers. I wanted to share the good news, the outcomes out of that meeting. We're in the process of producing a series of reports which are now being written up as articles of publication. We've had very good news since October. It's really remarkable. It impresses me in terms of how fast these things are going. We've had three articles accepted for publication, one on nomenclature, dealing with the things you're dealing with, and this is interpreting it for the intellectual disabilities field in many ways in terms of terminology. One on advanced dementia and end-of-life care, an area we're wrestling with, what is the transition point when you're going down the road with declining capabilities as a result of dementia and when do you have to introduce end-of-life issues in terms of palliative care, hospice? We've got an article coming out that's been accepted. We have another one that's been accepted on national plans, which essentially is promoting inclusion of intellectual disabilities within national action plans like we have done in the United States and are doing in some other countries.

Several other articles are in the works. They are in review actually. One on the general area of advanced dementia, and another one on proposed diagnostic services in terms of what happens when you diagnose dementia in a person with intellectual disabilities and what services are needed, and a complementary article on family supports, what do families need, and hopefully we can stimulate both the national planning and service agencies, administrative groups, and things like that in terms of looking at this. I wanted to share some good news in terms of what we're doing, also kind of say, look, materials are out there. We'll make them available on our website and nationally and internationally and hopefully that knowledge now coming out of our experts is going to be infused into iterations of the national plan here in the United States as you begin to work on the 2007 plan for--sorry, 2017 plan--I'm 10 years behind. We're doing it at no cost basically, all volunteers on our free time, whatever we have. It's not a big budget item. I would challenge other groups working with you in terms of dementia practices and services to do the same thing. Thank you.

Feng-Yen Li

Good afternoon, I'm a medical specialist from the Physicians' Committee for Responsible Medicine, a nonprofit based in D.C. working to advance medical research. So, as you all know, clinical trials play a central role in helping us reach our goal of having an effective treatment for Alzheimer's by 2025. However, we want to point out four caveats with current clinical trials, doing greatly to impede development of effective disease-modifying treatment. First is most clinical trials usually start in animal models that don't recapitulate human disease, and we often see that treatments are found to be effective in those animal models but often fail in humans in clinical trials. The second point has been mentioned this morning which is that chronic conditions associated with Alzheimer's disease are often excluded in these clinical trials. This can lead to treatments found to be effective in clinical trials but later would not be broadly applicable to the general population. The third point I want to make is that drug targets that are being used right now are often based on the rare genetic defects associated with aging, the inherited form of disease, and not the common form which we see in the general population. Yet the drugs that are--the drug candidates--are being tested, usually tested, in people with the common form of disease who may or may not have genetic risks. And this can lead to treatments failing in clinical trials in late stage or if we have successful intervention from a clinical trial it may not be broadly applicable to most people. The fourth and last point I want to make is that clinical trials usually aim to modify the Alzheimer's disease pathology rather than the lifestyle factors associated with Alzheimer's. Even though beta amyloid and tau are important disease hallmarks, they may have pathological consequences. The treatments will often fail to modify the disease or only temporarily decrease symptoms. Think we need to increase more clinical trials that are targeting the life--that aim to develop nonpharmacological interventions to address lifestyle factors, such as diet and exercise, because these can be developed more quickly and have great potential to reduce disease burden in a cost-effective manner and certainly will help us reach the goals of finding an effective treatment by 2025. Thank you so much.

Jodi Lyons

For those who don't know me, I'm Jody Lyons, author and care consultant who helps older adults find care they need throughout the country. Today I'm here to talk about the behavioral and psychological symptoms of dementia and then ask for help from the Council in dealing with that. As many of you know, there are many people who get violent or angry and become a danger to themselves and others due to the symptoms of dementia. They can't always be redirected. They can't always respond to nonpharmacological assistance and sometimes need pharmacological help. Many times--we've all seen this--it involves the police, handcuffs, pretty scary situations because the behaviors become worse than the EMTs [emergency medical technicians] can handle. We need to be able to identify the triggers, identify appropriate treatments and responses, but here's where I need your help, and I'd like to specifically ask for help from this Council. These are the people who can solve these problems.

As you know, the system's really not set up to deal with behavioral symptoms. For example, there are short-stay programs for medication adjustment, but very often those specialized communities are private-pay only and they can be upwards of \$10,000. Medication adjustments can be done in short-term rehab[ilitation], but Medicare only pays for that if the person has had a qualifying hospital stay and then also needs help with PT [physical therapy], OT [occupational therapy] and speech. Or you can have the medication adjustments done in a hospital. Only some hospitals can do that. And hospitals don't often want to admit somebody who's there with bad behaviors, posing a danger to themselves and the staff and everything else. And then we have the whole observation status where somebody may go into the hospital to try to get their behaviors regulated, to get their medications adjusted, check for infection, look for UTI [urinary tract infection], look for C. diff [*Clostridium difficile*], deal with those things and do the psychological behavioral issues and deal with all those but often get stuck on an observation bed, which means they don't qualify for short-term rehab. And when you have somebody who is decompensated in the hospital because they have been flat on their back for 10 days, they need PT and OT but don't qualify anymore. So, what I'm asking for today is for this Council to help identify ways that Medicare can pay for medication adjustments in somebody who is experiencing behavioral and psychological symptoms of dementia, without necessarily having to have a qualifying hospital stay. And without having to actually be admitted to the hospital. Perhaps an observation bed would work, but some way to get the people the help they need for medication adjustment without having to pay for the qualifying hospital stay. Thank you very much. I appreciate it.

Susan Peschin

I serve as president and CEO of the Alliance for Aging Research. Thanks for the opportunity to make a public comment. I have just a couple thoughts for the Council to please consider today. One of them is a rehash from last October. I'm going to ask again, once again, if you would consider having Dr. Hodes and the NIH representative include data on clinical trial recruitment and participation numbers for each NIH-funded Alzheimer's disease trial as part of the federal updates moving forward, or certainly at least within the Research Subcommittee if you don't want the public to see. It's

interesting for Dr. Ryan to provide the overall numbers of 150-plus trials, seeking 70,000-plus volunteers, but I think it would be much more helpful to see if some trials have more luck with recruitment than others and explore why is that. These reports ideally would include progress on recruitment of minority participants.

And another completely different area, I wanted to suggest that the Council consider exploring the creation of a Medicare reimbursement for health care providers to cover their time counseling patients about clinical trials. It takes a while to talk through this, explain it, and the likelihood of them doing it is, you know, going to be much higher if you provide some type of incentive. Or to explore if there's a term that could include time for this type of counseling. There is concern by some doctors, particularly under Medicare, that they may lose patients to trials. That means a loss in their business, so it's important to address that issue as well, whether it's possible to sort of somehow wrap them into any trial their patient goes into. These are issues that CMS or MedPAC [Medicare Payment Advisory Commission] could explore together. A great deal of time was spent to identify approaches for patient attribution that would be acceptable to providers. So we think that might be able to be a starting point for alleviating some of these concerns. I agree with Mary and other folks on the panel here today. I was thrilled to hear about expanding outreach efforts on Alzheimer's disease clinical trial recruitment beyond the ADRD communities. We think there's more opportunity for clinical trial education if efforts expand to the broader aging network, and including, you know, everything that people have suggested so far, but also senior centers and also I think state health insurance programs throughout the year. They educate folks about Medicare, and even during open enrollment of Medicare, it would be great if there were some type of educational effort to encourage folks to get involved in research for themselves and for future generations.

My organization is partnering with PhRMA [Pharmaceutical Research and Manufacturers of America] to develop a short pocket film, which is a short animated film, specifically about older adults and clinical trials, and we have an expert panel from NIH and other agencies that help us review these, the content in them, and it's going to be available for free, and we hope that all of you will use the tool. One more idea that I had around clinical trial recruitment was whether or not HHS could ask the agencies that are under its purview to include a "find out about research opportunities" banner that includes the ClinicalTrials.gov button on the front page of the website for CMS, HRSA, all the agencies that fall under HHS, if it's really a priority for HHS. That would be a great resource and probably a relatively low-hanging-fruit thing to do. I had one more very brief comment. Just felt it was necessary in the times that we're in, I just wanted to say to the federal members and staff that serve on this Council and to all your colleagues back at the agencies where you work that the Alliance for Aging Research believes the work you do is important, and we believe it's worth defending. We have hope that this new administration and Congress are going to share our sentiment on several of the research funding, clinical development, and health care issues that matter to us, and we look forward to working with them on those issues. They are probably going to disagree on some other issues, but nothing's going to prevent us from speaking out and standing up for what we know is right. So I wanted to thank you for the

work that you do and know, please know, that we support you. Thanks so much for allowing me to make the comments.

Mary Anne Sterling

I'm always the tall one in the group. I'm Mary Anne Sterling. I wear many hats. I'm a family caregiver, a small business owner, an adviser for the AD-PCPRN that you heard about this morning from our friend Rachel. My husband and I have had three out of four parents impacted by this disease. That's obviously why you see me often here. So I'm going to address the 800-pound gorilla in the room. It's difficult for many families struggling to care for someone with dementia to focus. The first 2 weeks of the new administration left us wondering what an uncertain future will bring, and as I'm writing this, the Affordable Care Act is in serious jeopardy. You ask most Americans what impact will the repeal of the Affordable Care Act have on people with dementia and their families, most folks have never even considered that it would have an impact. People need to know this sort of stuff. So my friends at the Leap Coalition did a wonderful job outlining the facts in a concise brief. Repeal could impact goals and recommendations of this Council for years to come. Here are the important provisions hanging in the balance that everyone needs to be aware of and those that are most important to my family:

- Of course, the Medicare annual wellness visit, let's start there, with a cognitive assessment, so we can detect issues early, before families are in crisis.
- Protection for preexisting conditions--this is critical for adults with early onset dementia and of course their caregivers.
- Innovative models of care, so we can find a combination of affordable care and services that works for people with dementia and their caregivers.
- Next, Medicare-Medicaid care coordination, [which is] critical for families with loved ones in later stages of dementia and something I struggled with last year.
- Medicaid expansion, so those with dementia can remain in the community while preventing the impoverishment of their spouses.
- Funding for patient-centered research on dementia--as you may remember, I'm a patient research partner and ambassador for PCORI [Patient-Centered Outcomes Research Institute] and AD-PCPRN doing important clinical research and must continue to do so.
- New requirements for nursing homes, those aimed at improving quality of care we expect for our loved ones.
- And finally, support for young adult caregivers so they can remain on their parents' insurance through the age of 26; this is an ever-growing population at the moment.

So, in this new era of alternative facts, let's not leave Alzheimer's families in the dark to find the rug pulled out from under them.

Nadine Tatton

Hi. I'm Nadine Tatton from Frontotemporal [Association for Frontotemporal Degeneration]. For 2 minutes, forget everything about recruiting for Alzheimer's disease

clinical trials this morning and step over to the related dementias playing field. It's a rare disease--50,000-60,000 people with FTDs, compared to Alzheimer's with 5 million. FTD is a group of disorders affecting behavior, cognition, language, and movement; each is a subtype that makes them more rare. Clinicians put together language variants of FTD, FTD dementia. That's what I'll talk about now. One of our big problems is amyloid and tau protein as your underlying pathology, life is not easy. Some people have tau, half present with tau, others have TPD [transactive response DNA binding protein] 43, and we didn't have a simple test or imaging to tell which one you have. So all of those things together give us distinct challenges when it comes to recruiting for clinical trials on FTD. The first one is recruiting adequate numbers, for us to get a few hundred people in a clinical arm trial that requires a multisite effort, and increasingly that includes multisite plus international, so it's a different ballpark altogether. Getting the right patient in the right trial is also a problem for us because we don't know what the underlying pathology is. So what we're relying on now is the small segment who have a genetic mutation, slicing the rare disease pie even smaller. The other problem is that we've got a narrow window of opportunity--making an early and accurate diagnosis is difficult. We don't have biomarkers yet and also for people that are diagnosed, they live on average 6-12 years after the diagnosis. So that gives us a short amount of time that we can recruit them to a trial. Finally, retaining people in a trial--because we've got that narrow window, because the disease progresses so quickly, daily activity of living, all the simple things you take for granted, are severely compromised as FTD goes forward. Starting a trial and to be able to stay in and be mentally and physically capable of completing the trial are challenges, particularly as it comes to informed consent, not to mention multiple travel and imaging and other things at a trial that's required of them. It's a different world and means we need to design better trials for these groups. And that could benefit Alzheimer's disease as well.

Finally, I'd like to thank our friends and colleagues at NIA, NIAID [National Institute of Allergy and Infectious Diseases], and NCATS [National Center for Advancing Translational Sciences] for the funding coming toward FTD research making a huge difference for us. One challenge we don't have is that we have an active engaged community who have stepped up every time we've asked them to participate in any kind of research study. For us, every drug intervention trial for FTD, since we have no approved drugs, everyone is a mini moonshot for us, and we're thrilled to have them, so thank you very much.

NATIONAL RESEARCH SUMMIT ON CARE, SERVICES AND SUPPORTS FOR PERSONS WITH DEMENTIA AND THEIR CAREGIVERS: UPDATE

Laura Gitlin, Ph.D. (Johns Hopkins Center for Innovative Care in Aging)

The National Research Summit will take place October 16-17, 2017, in NIH's Natcher Building. Anonymous donors funded an administrative support person. The Foundation for the NIH (FNIH) will raise funds for and promote the summit, including creating a "save-the-date" announcement. Ellen Blackwell secured graphic design support from CMS to create a logo that reflects the theme of building the evidence base. The goal for

the summit is to identify what we know and what we need to know to accelerate development, evaluation, translation, implementation, and scaling-up of comprehensive care, services, and support for persons with dementia, their families, and caregivers.

The organizers use an iterative structure and an “all-in” approach to planning that will influence the next steps after the summit. There is broad representation among planners, but the Steering Committee is still seeking representation from people with dementia. The Steering Committee reviews progress, identifies topics for consideration, and makes recommendations. It established six stakeholder groups, each co-chaired by a Council member, to discuss topics and speakers: family caregivers, persons with dementia, service providers, states, payers, and workforce. Staff from RTI International will document the stakeholder group meetings and present feedback to the Steering Committee and the Council. After the summit, these groups will weigh in about research recommendations and disseminating findings.

Katie Maslow (National Academies of Sciences)

Six pre-summit activities are underway, including several scientific meetings that will provide foundational knowledge. Organizers will capture the findings and recommendations of the following presummit activities, post them online, and determine how to incorporate them into the summit:

- Evidence for Home-Based Dementia Care: Systematic Literature Review and Think Tank (Drs. Lyketsos, Samus, & team, Johns Hopkins University).
- Determinants of Behavioral Symptoms: Systematic Literature Review (Dr. Kolanswki and team, Penn State University).
- Diversity and Alzheimer’s Disease Caregiving Conference: Race/Ethnicity and Caregiving (Dr. Meyer, University of California, Davis).
- Caregivers of Persons with Intellectual and Developmental Disabilities and Dementia (Dr. Janicki, NTG).
- 2015 Survey Data on Family Caregivers of Persons with Dementia (National Alliance on Caregiving, Alzheimer’s Association).
- Methodological Considerations in Research on Care and Services (Dr. Frank, PCORI).

Maria Carillo, Ph.D., will initiate the summit by outlining the biomedical research context. Other featured speakers will emphasize the heterogeneity of individuals with dementia and their caregivers. The six summit sessions will cover a wide range of topics; some overlap may need to be addressed.

Organizers have named three chairs responsible for tracking key cross-cutting issues to ensure those topics do not get lost over the course of the summit:

- Technology: Dr. Czaja.
- Race/Ethnicity/Culture: Dr. Hinton.
- Etiologies/Disease Stage: Angela Taylor.

There is discussion about adding a cross-cutting chair for family caregivers.

The summit co-chairs are responsible for identifying session content and structure, speakers, and panelists, then feeding that information to the Steering Committee for approval. Speakers and co-chairs will develop recommendations and ensure the summit sessions are organized around those recommendations. Stakeholder groups will be finalized and convene at least once in February (and periodically after that). Organizers will begin working with FNIH; for example, FNIH will reach out to organizations that funded previous NIH summits on Alzheimer's disease.

Comments and Questions

- **Ronald Petersen:** Does the summit envision creating recommendations that can be translated into milestones? **Dr. Gitlin:** The summit will follow the model of NIA summits in formulating recommendations, but with more input from stakeholder groups and close attention to what happens to the recommendations after the summit. The recommendations should inform the work of many organizations and the NIH institutes and centers, so we need to think about how to link our recommendations to their work.
- **Jennifer Mead:** Does the location lend itself to live streaming or a webcast of the event? **Dr. Gitlin:** Yes. We are discussing whether to stream the summit live or provide it via an archive. **Ms. Khillan:** As a NAPA-sponsored meeting, the summit is open for public comment, so the Office of the Assistant Secretary for Planning and Evaluation (ASPE) is considering the requirements and logistics.

2016 ADRD MILESTONES

Roderick Corriveau (National Institute of Neurological Disorders and Stroke [NINDS])

NINDS complements the NIA's role in the NIH response to the National Plan, which calls on NINDS to convene stakeholders to refine and add milestones based on recent scientific discoveries. The research portfolio of NINDS included \$66 million for Alzheimer's disease and \$36 million for ADRD in fiscal year 2015. NINDS coordinates the triennial summits on ADRD. The NIH Alzheimer's disease and ADRD summits inform the National Plan, which is updated annually. The National Plan and its milestones inform NIH's annual bypass budget, which determines funding for research around the National Plan goals.

In preparation for the 2016 ADRD summit, NINDS presented draft recommendations in advance to allow for public input. Following the conference, organizers incorporated the feedback into a report to HHS with recommendations and milestones. That report is being prepared for publication. The final report includes fewer recommendations and

milestones than originally proposed, but all the suggestions are important research goals. The recommendations were prioritized in recognition of the timelines needed to achieve Goal 1 of the National Plan by 2025. However, timelines are independent of priority; that is, the priority does not change depending on how much time it takes. Both aspirational and operational (or achievable) recommendations are important and necessary.

Resources for NIH's Alzheimer's disease and ADRD research have increased each year since 2011, with much of the funding going to NINDS but also to NIA. The two institutes work together to oversee shared research funds by supporting specific calls for research or inviting investigator-initiated research. A number of NINDS research initiatives respond to National Plan milestones. One major effort is the creation of a national consortium to identify biomarkers of vascular contributions to cognitive impairment and dementia (VCID) that can be used in clinical trials. The science of VCID cuts across Alzheimer's disease and other comorbidities. Other NINDS research initiatives target the multiple etiologies that contribute to Alzheimer's disease and ADRD. A joint NIA/NINDS project is addressing health disparities in Alzheimer's disease and ADRD.

A key goal that came out of the 2016 ADRD Summit was to establish more effective communication between NIH and nongovernmental organizations (NGOs) on activities and progress toward Alzheimer's disease and ADRD goals. To that end, NINDS publicly posted the summit milestones and the criteria for success. NINDS will present annually to the NAPA Council on milestones beginning in 2017. It will also convene NINDS, NIA, and NGOs in annual meetings to share information. A special joint session at the 2016 summit resulted in a recommendation, adopted by the Council, to standardize terminology for cognitive and dementing disorders. Finally, NIH is addressing cognitive health in other ways, such as the Mind Your Risks campaign, which raises awareness that controlling blood pressure in mid-life can decrease the risk of stroke and dementia later in life.

Comments and Questions

- **Ronald Petersen:** NIA focuses more on clinical research in Alzheimer's, and NINDS funds more basic research. Do FTD and related dementias fall through the cracks? **Dr. Corriveau:** No. NINDS and NIA are open to all kinds of research. **Dr. Hodes:** Both institutes solicit and support research and coordinate efforts.
- **Myriam Marquez:** Is there any international research to inform the work of United States investigators, and if so, how is it shared? **Dr. Hodes:** There is a high level of international collaboration on ADRD. For example, for large scientific efforts, the Alzheimer's Disease Neuroimaging Initiative represents lots of programming on neuroimaging. NIA harmonizes research across many nations so we can look at more people and more diverse populations. The Dominantly Inherited Alzheimer's Network identifies rare, early-onset cases and brings

together people around the world for research. Pooling results of studies internationally has informed an understanding of genetics. In this area, international collaboration is enormously important. **Dr. Dunn:** On the regulatory side, there is global harmony around research objectives, funding, and goals. ADRD is a particularly important area where we need to maximize our resources and place high priority on the harmonization of regulations.

- **Ronald Petersen:** Is there any follow-up on United States involvement with the European Union Joint Programme--Neurodegenerative Disease Research (JPND)? **Dr. Hodes:** The JPND is a multinational collaborative effort around ADRD that includes Canada and Australia. The JPND announced its next target research priority, which parallels NIH's FOAs. We are committed to finding ways to coordinate and collaborate around the scientific efforts of JPND.

FEDERAL WORKGROUP UPDATES

Long-Term Services and Supports

Erin Long (ACL)

The Alzheimer's Disease Supportive Services Program (ADSSP) and Alzheimer's Disease Initiative--Specialized Supportive Services (ADI-SSS) grants funded by ACL extend across the country. ACL is planning to present education on improving care and services for people with dementia and their family caregivers at the March 2017 meeting of the Aging Society of America (ASA). It is coordinating a special electronic edition of ASA's journal on Alzheimer's and dementia. The National Alzheimer's and Dementia Resource Center kicked off a national webinar series in January. The fifth annual webinar series on dementia resources and research begins March 1; it targets professionals in public health and research. ACL's *What Is Brain Health?* campaign has a new spokesperson, actor Hector Elizondo, and several activities targeting Hispanic communities. The effort has produced several videos and public service announcements, which are available online and received recognition awards.

Ellen Blackwell (CMS)

CMS released new data on Medicaid's LTSS and home and community-based services (HCBS) programs. We are over 50% now in terms of beneficiaries who receive Medicaid LTSS, including institutional care and HCBS, which demonstrates real progress. CMS provided more guidance and new options on how to facilitate HCBS through State plans. Also, CMS issued Medicaid guidance on unsafe wandering and exit-seeking. While the guidance is aimed at people in home and community-based settings, it is also useful for nursing homes, hospitals, and families. It offers suggestions on how to manage people in restricted settings by maintaining a community integration focus.

Erin Long (for Bruce Finke, Indian Health Service [IHS])

The IHS program, Resources for Enhancing Alzheimer's Caregivers Health in Tribal Communities (or REACH into Indian Country), has trained 160 coaches in intervention and certified 60. It has already reached 45 communities toward its goal of 50 by February 2018. To date, 46 caregivers have enrolled, and that number should rise as more attention turns to raising awareness about new services available. In November 2016, IHS and CMS cosponsored a tribal meeting in Minnesota (funded by ACL) on LTSS, including access to technical assistance. Also in November, IHS held a core course on dementia; the community-based track was well received, but clinician participation was limited, primarily because clinicians had limited resources for travel. A workforce development track is needed. IHS is evaluating alternative training models to engage in geriatric workforce development programs in Indian country. It recently worked with the Arizona Geriatrics Workforce Enhancement Program to coordinate training and outreach. The IHS and U.S. Department of Veterans Affairs (VA) Rural Interdisciplinary Team Training effort provided intensive team training for ten IHS and tribal rural facilities.

Richard Hodes (NIA)

The prevalence and incidence of dementia have decreased in the United States and globally since 2000. While impressive, this pattern will be dwarfed by the increasing number of older people, so the burden of disease will not change. However, the change does provide an opportunity to look at potentially malleable factors that led to the decline. One factor in the decline appears to be regulation of cardiovascular disease, but that does not account for very much of it. The role of education is probably the strongest contributor, as higher education is associated with lower risk, and older adults are more highly educated now. Various aspects of care in nursing homes have been a topic of discussion by this Council. There have been significant, dramatic decreases in use of feeding tubes in nursing home residents with advanced dementia based on evidence that the practice does not extend life and compromises quality of life. A survey demonstrated the disproportionate impact of dementia on family and unpaid caregiving to older adults. The intensity of care is higher in residential than community-based settings, especially when family members take on the burden of caregiving. Having data may help us move forward and can be a benchmark for assessing progress.

Comments and Questions

- **Jennifer Mead:** Are ACL grants for ADSSP and ADI-SSS supported by funds tied to the Affordable Care Act, and if so, is the future of those programs up in the air? **Ms. Long:** We are prepared to move forward for this year on a conditional basis.
- **Ronald Petersen:** What accounts for the lack of clinician attendance at the Minnesota conference? **Richard Haverkate:** Clinicians' offices are so short-staffed and underfunded that it is hard for clinicians to leave the office for training. **Ms. Walberg:** IHS has some training available on demand; we used an

onsite trainer who was very good, and it had a big impact on service delivery in Minnesota.

- **Laura Gitlin:** In the REACH into Indian Country initiative, is the difference between the number of people trained and certified a function of timing or a gap that needs to be addressed? **Ms. Long:** Some of both. In some cases, we do a combination of training and certification. In others, individuals do the training remotely, and it is challenging to get them to complete certification. We are doing some peer support to encourage them. As we scale up, we will certify more people. The past 18 months have focused on getting interventionists and coaches trained; now, more attention is being paid to caregivers.
- **Ronald Petersen:** One reason why prevalence figures do not always align with experience in the field is that definitions may be expanded to include milder forms of disease. Definitions and biomarkers are in flux, which makes it harder to communicate with the public. **Dr. Hodes:** Yes, there are a wide range of numbers on the incidence of dementia, but we can live with that. Longitudinal studies use the same criteria over time in the same cohort, so they provide good information about trends.

Clinical Services

Marianne Shaughnessy (VA)

The Veterans Health Administration (VHA) Dementia Steering Committee updated its recommendations in September 2016 after a long process to reach consensus. Some old recommendations were eliminated and new ones added. The updated recommendations are available online at the VHA's Office of Geriatrics and Extended Care website; they address recognition of dementia, diagnosis, treatment, care coordination, administrative matters, research, and education. Also, VHA updated a fact sheet in December 2016 on detecting cognitive impairment. It does not recommend screening asymptomatic individuals but lists warning signs and describes elements of a structured diagnostic evaluation if warning signs are present. The factsheet is available on the VHA's National Center for Health Promotion and Disease Prevention website.

Ellen Blackwell (CMS)

CMS announced a new Medicare-Medicaid Accountable Care Organization model that applies to beneficiaries covered by both programs ("dual eligibles") and includes HCBS. The 2017 physician fee schedule allows enhanced payment for improved care planning for people with Alzheimer's and cognitive impairment. The fee schedule also includes notable behavioral health enhancements. In December, CMS requested public input on a new proposed model of person-centered community care for dual eligibles under the Programs of All-Inclusive Care for the Elderly (PACE) Innovation Act and asked for opinions on expanding the PACE model. Also in December, ASPE and CMS published a report on the effect of socioeconomic status on Medicare quality and resource use measures. Socioeconomic status has immense consequences for attribution in health care plans and fairness in terms of addressing health disparities. In November, CMS

issued its new Person and Family Engagement Strategy, which describes what CMS is doing to ensure beneficiaries are in the driver's seat. As a follow-up to the strategy, the Innovation Center put forth two beneficiary engagement models on shared decision-making and direct decision support.

The National Partnership to Improve Dementia Care in Nursing Homes was the subject of a December teleconference in which a CMS expert discussed behavioral health requirements under the Long-Term Care Facility rule. The audio recording and transcript are available online. The National Partnership's quarterly trend data show continued progress in reducing the use of antipsychotic medication. The Measures under Consideration list for 2017 was finalized in November. It includes an item on safety concern screening and follow-up for patients with dementia.

Comments and Questions

- **Laura Gitlin:** Does the Medicare payment of behavioral health cover delivery of evidence-based approaches to prevent and manage behavioral symptoms in people with dementia, and is it limited to physicians? **Ms. Blackwell:** It applies to qualified providers. Because it is a new initiative, it is likely that additional guidance will be forthcoming.
- **Helen Matheny:** The Council has long supported new codes for care planning. Will the new codes be used in combination with or in place of office visit codes? **Ms. Blackwell:** Medicare is working on guidance and will reach out to providers when it finalizes its thinking.

ADRD RESEARCH: TRANSFORMING ALZHEIMER'S DISEASE THERAPY DEVELOPMENT

Richard Hodes, M.D. (NINDS)

The history of failed phase-3 studies of drugs for Alzheimer's disease demonstrates the need to better understand the underlying mechanisms of the disease, which requires a robust pipeline of research. A strong pipeline supports research at every stage, including a handoff to the private sector for approval. The Accelerating Medicines Partnership (AMP) is a collaboration between NIH, FDA, manufacturers, and NGOs to translate genomic and other data into drug targets and biomarkers. The Molecular Mechanisms of the Vascular Etiology of Alzheimer's Disease is a consortium of cross-disciplinary research teams that share data rapidly and broadly. Another study is characterizing new biomarkers in ongoing clinical trials. The AMP-Alzheimer's Disease Knowledge Portal aims to release large data sets publicly so others can use them.

Globally, researchers are trying to address concerns about the nonreproducibility of data and the lack of translation of findings from preclinical to clinical trials. The Alzheimer's Disease Preclinical Efficacy Database aims to collect sufficient information from preclinical trials to allow researchers to reproduce the findings; NIH plans to

expand the database to include prepublication and published data, all available via an open-access database. It is hoped the effort will help develop more reliable models. The Alzheimer's Disease Translational Center for Animal Model Resources and Preclinical Efficacy Testing Multicomponent Center will focus on animal models and make all data available to the broader research community. Other new initiatives include the Alzheimer's Biomarker Consortium--Down Syndrome, a 5-year program to track Alzheimer's-related brain changes in adults with Down syndrome, and the Alzheimer's Clinical Trials Consortium, which will create a new infrastructure to support clinical trials. A number of new funding initiatives from NIA and NINDS relate to ADRD.

Comments and Questions

- **Laura Gitlin:** Are the new initiatives limited to drug discovery? **Dr. Hodes:** They are open to pharmaceutical and nonpharmaceutical interventions.

2017 RECOMMENDATIONS

Rohini Khillan (ASPE)

The Council voted on its final 2016 Recommendations at the April 2016 meeting and submitted them to the HHS Secretary and Congress in May. The list of Congressional representatives who received the recommendations was expanded to include all those who expressed interest in Alzheimer's disease as well as key committee members. For each of the 12 recommendations, subcommittee chairs wrote brief overviews; each recommendation was accompanied by a list of specific actions. The 2016 recommendations were included as an appendix to the National Plan update along with a formal response from the federal partners. The 2017 update will clearly indicate that the responses represent only the responses of federal partners. We will work on a mechanism to allow for public comment from non-federal organizations, perhaps through an online comment page or publication in the *Federal Register*. Those responses will be posted online.

There has been some discussion about categorization of recommendations and about adding suggestions for states and localities. Two states have presented their state plans and expressed a desire to collaborate.

Comments and Questions

- **Ronald Petersen:** The workgroups will generate recommendations for review by the Council at the April 2017 meeting. This process is malleable; if you have suggestions about it, including how to encourage public comments, please make them.
- **Jennifer Mead:** Council members would like to have the draft recommendations to review about a week before the April meeting. One day before the meeting is not enough time for review. How would categorization work? **Ms. Khillan:** The

Council can categorize recommendations according to the intended audience, which would help distinguish which actions various stakeholder can undertake.

- **Angela Taylor:** Council members should come to the April meeting prepared to discuss the recommendations and modify them. It would be great to have a draft of the federal responses so that Council members can revise the recommendations as needed to ensure they are feasible. **Ms. Khillan:** The subcommittee chairs have input from federal partners during their calls. However, the federal partners should not influence the Council members' recommendations.
- **Gary Epstein-Lubow:** How would the Council address public comments received after the recommendations were approved? **Ms. Khillan:** It is up to the Council how to handle public comments. Comments could be posted online; the Council could respond in July if desired. **Dr. Epstein-Lubow:** Would it be possible to discuss public comments and federal responses at a subsequent meeting? **Ms. Khillan:** The National Plan is expected to be completed by July, so the Council could discuss the federal responses at its July meeting.
- **Ronald Petersen:** What is the status of the National Plan in relation to the administrative transition? **Ms. Khillan:** Last year, the National Plan came out in August, and that timeline worked well with the NIH's bypass budget timeline. It is not clear whether the clearance process will change with the new administration. Confirmation of a new HHS Secretary will affect leadership of all divisions.

CONCLUDING REMARKS

Dr. Petersen adjourned the Council meeting at 3:53 PM.

Minutes submitted by Rohini Khillan (ASPE).

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

PARTICIPANTS

Advisory Council Members

Present

Ellen Blackwell (for Shari Ling, afternoon)

Billy Dunn

Gary Epstein-Lubow

Laura Gitlin

Richard Haverkate

Richard Hodes

Harry M. Johns

Ruth Katz

Rohini Khillan

Shari Ling, (morning)

Erin Long

Myriam Marquez

Helen M. Matheny

Jennifer Mead

Deborah Olster

Anthony Pacifico

Ronald C. Petersen, Chair

Marianne Shaughnessy

William Spector

Angela Taylor

Sowande Tichawonna

Donna Walberg

Kurt Greenlund

Joan Weiss

Mary Worstell

Absent

Richard Allman

Bruce Finke

Lisa McGuire

Geraldine Woolfolk

Presenters

Roderick Corriveau

Keith Fargo

Jessica Langbaum

Katie Maslow

Rachel Nosheny

Laurie Ryan

George Vradenburg

Public

Alex Alexander	Matthew Janicki	Sarah Milberg
Dawn Beraud	Sophia Jeon	Douglas Pace
Julia Brown-Georgi	Beth Kallmyer	Susan Peschin
Thomas Buckley	Melinda Kelley	Suzanne Petarcaska
Rachel Conant	Jonathan King	Chip Rose
Phil Cronin	Ian Kremer	James Scott
Katie Donnini	Kelley Landy	Matthew Sharp
Dayne DuVall	Debra R. Lappin	Nina Silverberg
Elena Fazio	Christopher Laxton	Sarah T. Smith
Jordan Gladman	Robert LeRoy	Eric Sokol
Phyllis Greenberger	Feng-Yen Li	Mary Anne Sterling
Mary Hogan	Charlene Liggins	Nadine Tatton
Heidi Holt	Jodi Lyons	Courtney Wallin
Samantha Hunter	Eliezer Masliah	Benjamin Wiley

February 3, 2017 -- Advisory Council Meeting #23

The meeting was held on Friday, February 3, 2017, in Washington, DC. The theme of this Advisory Council meeting was clinical trials for Alzheimer's disease and related dementias and recruitment challenges. Additional afternoon presentations included updates on progress towards a Care and Services Summit, federal workgroup updates, and preparation for the Advisory Council's 2017 Recommendations, due in April 2017. Material available from this meeting is listed below and is also available at <https://aspe.hhs.gov/advisory-council-alzheimers-research-care-and-services-meetings#Feb2017>.

Comments and questions, or alerts to broken links, should be sent to napa@hhs.gov.

General Information

Agenda	[HTML Version] [PDF Version]
Meeting Announcement	[HTML Version] [PDF Version]
Meeting Summary	[HTML Version] [PDF Version]
Public Comments	[HTML Version]

Handouts

Panelist Bios	[HTML Version] [PDF Version]
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Presentation Slides

2017 Recommendations	[HTML Version] [PDF Version]
Alzheimer's Association TrialMatch	[HTML Version] [PDF Version]
Clinical Services Subcommittee Federal Update	[HTML Version] [PDF Version]
Clinical Studies Recruitment Strategy	[HTML Version] [PDF Version]
Development and Use of Registries to Accelerate Enrollment into Alzheimer's Trials	[HTML Version] [PDF Version]
Long-Term Services and Supports Committee Update	[HTML Version] [PDF Version]
National Recruitment Strategy	[HTML Version] [PDF Version]

NINDS Update	[HTML Version] [PDF Version]
Randomized Controlled Trials for Alzheimer's Disease	[HTML Version] [PDF Version]
Strategies to Facilitate Recruitment and Screening for Alzheimer's Clinical Trials	[HTML Version] [PDF Version]
Transforming AD Therapy Development	[HTML Version] [PDF Version]
Update National Research Summit on Care, Services and Supports for Persons with Dementia and Their Caregivers	[HTML Version] [PDF Version]

Videos

Welcome thru Perspectives	[Video]
Rachel, Jessica, George Presentations	[Video]
Keith Presentation and Panel Discussion	[Video]
Public Comments	[Video]
Care Summit and Milestones	[Video]
Federal Workgroups and Adjourn	[Video]

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