

Advisory Council on Alzheimer's Research, Care, and Services

October 15, 2012

NAPA Research Update

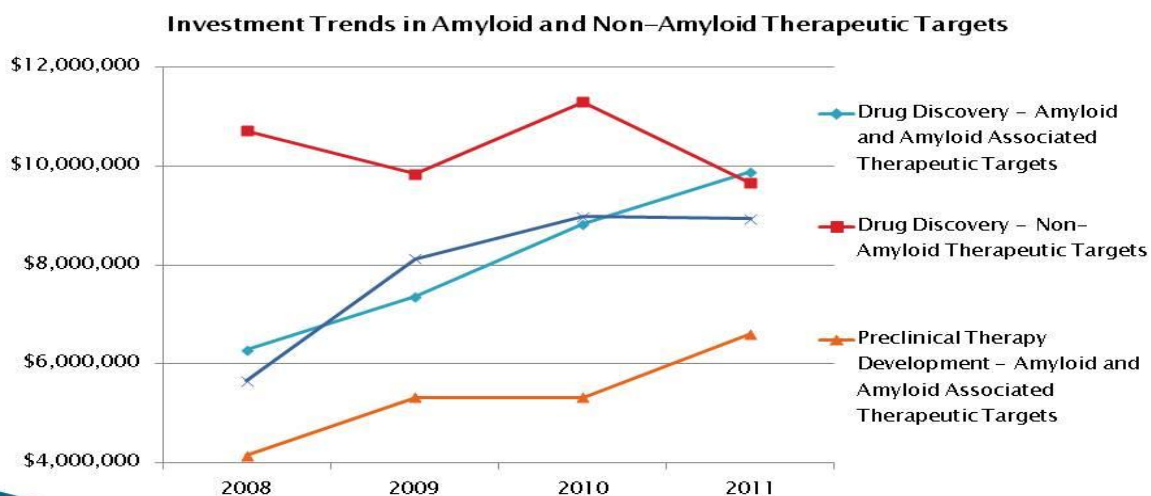
Richard J. Hodes, M.D.
Chair, Research Subcommittee



International Alzheimer's Disease Research Portfolio (IADRP)

- ▶ Developed by NIA in collaboration with Alzheimer's Association – <http://iadrp.nia.nih.gov/cadro-web/>
- ▶ Will enable funders of Alzheimer's research to coordinate planning, leverage resources, avoid duplication, and identify new opportunities for collaboration.
- ▶ Will give the public a full picture of the scale of ongoing research on AD.
- ▶ To date, includes only Federally funded and Alzheimer's Association-supported projects. Efforts are underway to include more domestic and international funders.
- ▶ Data Sharing Agreements with Alzheimer's Research UK (data to be uploaded later this month)

Category C. Translational Research and Clinical Interventions



White House Proposal for \$80 Million Additional AD Funding in FY 2013

- ▶ NIH is using the following process to ensure timely and most effective spending of the anticipated \$80M in additional funding for AD research for the current fiscal year:
 - Representatives from several NIH ICs worked together to identify areas of highest need/opportunity, informed by the Alzheimer's Summit and other input.
 - NIA took the lead on developing FOA concepts for presentation at NACA in September 2012.
 - Extra funding will allow NIH to support more grants through these or existing FOAs and/or investigator-initiated research.

FY 2013 AD Concept Clearance

- ▶ Genetic Analysis
- ▶ Target Identification and Validation
- ▶ Phase I Clinical Trials for AD Therapeutics
- ▶ Prevention Trials

AD Clinical Trial Enrollment Update

- ▶ NIA assessing successes, issues, and gaps in Alzheimer's clinical research recruitment/enrollment
 - AD Centers, AD Neuroimaging, NACC experience
 - Registries - current landscape
 - Strategies to increase enrollment of racial and ethnic populations - RCMARs and AD Centers
- ▶ Discussions underway with Federal agencies, grantees, and private organizations
- ▶ Request for Information (RFI) under consideration to help in workshop planning
- ▶ Internal planning with NIH, other agencies - late November 2012
- ▶ Workshop to develop action/implementation plan - early 2013

Alzheimer's Disease-Related Dementias Workshop

May 1-2, 2013, Natcher Auditorium, NIH Campus, Bethesda, MD

- ▶ NINDS, together with NIA, is planning a workshop to solicit input and develop recommendations on research priorities and timelines for AD-Related dementias.
- ▶ Outline of Workshop Topics:
 - FTD and AD-Related Tauopathies
 - Lewy Body Dementias
 - Vascular Contributions to AD-Related Dementias
 - Mixed Dementias
 - *Breakout Groups*
 - Clinically Important Diagnostic Challenges in Dementias
 - Health Disparities in AD-Related Dementias
- ▶ The workshop will define the state of the science and identify the critical opportunities and barriers in each of the dementias, whether basic, translational, or clinical.



Down Syndrome Research Update

- ▶ The Global Down Syndrome Foundation and the Alzheimer's Association hosted the workshop from September 13– 14 to bring together key scientists from the fields of Down syndrome and Alzheimer's research in Chicago. Widely attended, including NIA and NICHD staff.
- ▶ NIA and NICHD have begun planning for a research workshop on Down Syndrome and Alzheimer's disease in 2013.

Clinical Services Progress Report

Shari M. Ling M.D
Deputy Chief Medical Officer
Centers for Medicare & Medicaid Services (CMS)
Center for Clinical Standards & Quality (CCSQ)

2.B.2: Identify and disseminate appropriate assessment tools that can be used in a variety of outpatient settings including the Medicare Annual Wellness Visit, to assess cognition.

The Eight Instruments

- ▶ **Ascertain Dementia 8 (AD8)**
- ▶ **Brief Alzheimer's Screen (BAS)**
- ▶ **Short Blessed Test (SBT)**
- ▶ **Mini-Cog**
- ▶ **Mental Status Questionnaire (MSQ)**
- ▶ **Six-Item Screener (SIS)**
- ▶ **Short Test of Mental Status (STMS)**
- ▶ **Short Portable Mental Status Questionnaire (SPMSQ)**

Inclusion Criteria

- ▶ Less than or equal to 5 minutes to administer
- ▶ Free of charge with simple access
- ▶ Applicable to Medicare population
- ▶ Designed to assess age-related cognitive impairment
- ▶ Must assess memory + at least one other cognitive domain
- ▶ Validated in US community-based sample or primary care settings
- ▶ Post-validation used in US between 2001 – 2011

Medicare's Annual Wellness Visit (AWV) Components

- ▶ Detection of cognitive Impairment
- ▶ Health Risk Assessment
- ▶ Medical & Family History
- ▶ Providers & medications
- ▶ Biometric measurements
- ▶ Preventive service plan (5–10 yrs)
- ▶ Personalized health advice, referrals,
- ▶ Other elements determined appropriate by the Secretary and health education

U.S. Preventive Services Task Force

- ▶ **Screening for Dementia (2003)**

The USPSTF “concludes that the evidence is insufficient to recommend for or against routine screening for dementia in older adults.” Grade: I statement.

- ▶ **USPSTF Clinical Consideration:**

“Although current evidence does not support routine screening of patients in whom cognitive impairment is not otherwise suspected, clinicians should assess cognitive function whenever cognitive impairment or deterioration is suspected, based on direct observation, patient report, or concerns raised by family members, friends, or caretakers.”

- ▶ **Based on USPSTF recommendations and a general review of the literature at the time, this element is defined in implementing regulations as:**

- “assessment of an individual’s cognitive function by *direct observation*, with due consideration of information obtained by way of patient report, concerns raised by family members, friends, caretakers, or others.

2.D.1: Explore programmatically relevant dementia care guidelines and measures

PQRS # & Title	Description	Data Source
280 – Dementia: Staging of Dementia	Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period	Measures Group
281 – Dementia: Cognitive Assessment	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least within a 12 month period	Measures Group
282 – Dementia: Functional Status Assessment	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period	Measures Group
283 – Dementia: Neuropsychiatric Symptom Assessment	Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period	Measures Group
284 – Dementia: Management of Neuropsychiatric Symptoms	Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period	Measures Group

Physician Quality Reporting System: 2012 Dementia Measures Groups Measures

PQRS # & Title	Description	Data Source
285 – Dementia: Screening for Depressive Symptoms	Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period	Measures Group
286 – Dementia: Counseling Regarding Safety Concerns	Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled or referred for counseling regarding safety concerns within a 12 month period	Measures Group
287 – Dementia: Counseling Regarding Risks of Driving	Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period	Measures Group
288 – Dementia: Caregiver Education and Support	Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional resources for support within a 12 month period	Measures Group

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2.A.4: Strengthen the direct-care workforce – release training materials for nursing home direct care workforce

- ▶ Proactive efforts include collaboration with partner organizations around:
 - provider and prescriber training
 - surveyor training, review of surveyor guidance, protocols and challenges related to assessing compliance in these areas
 - research
 - quality measurement
 - public reporting
 - communication strategies such as local and national conference presentations, press releases
 - developing dissemination strategies in states and regions and a sustainable national plan for ongoing monitoring and evaluation of these issues

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Partnership Overview

- ▶ **Multidimensional approach includes:**
 - **Public Reporting**
 - ❖ First year goal: reduce prevalence rate of antipsychotic drug use in long-stay nursing home residents by 15% by end of 2012
 - ❖ Rates of nursing homes' antipsychotic drug use available on Nursing Home Compare (long-stay prevalence; short-stay incidence)

Current Partner Organizations

- ▶ AHCA
- ▶ AMDA
- ▶ LeadingAge
- ▶ Advancing Excellence
- ▶ ASCP
- ▶ Several universities
- ▶ Behavioral health management companies
- ▶ AAGP
- ▶ AGS
- ▶ NICHE
- ▶ Alzheimer's Association
- ▶ Consumer Voice, Center for Medicare Advocacy, LTCCC, CANHR, other advocacy organizations
- ▶ IOM
- ▶ APNA
- ▶ GAPNA
- ▶ NaRCAD
- ▶ AANAC
- ▶ AHFSA and several state survey agencies

Questions

- ▶ What should we collectively do to achieve better outcomes?
- ▶ What should we know that we might not?
- ▶ What quality measures will most meaningfully drive improvement towards better outcomes?
- ▶ Which outcomes are the highest priority to focus on?

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The Preferred Road to Diagnostic Coverage

- ✓ Provide adequate evidence that
- ✓ The incremental information obtained by new diagnostic technology compared to alternatives
- ✓ Changes physician recommendations
- ✓ Resulting in changes in therapy
- ✓ That improve clinically meaningful health outcomes
- ✓ In Medicare beneficiaries

The Preferred Road to Therapeutic Coverage

- ✓ Provide adequate evidence that
- ✓ A treatment strategy using the new therapeutic technology compared to alternatives
- ✓ Leads to improved clinically meaningful health outcomes
- ✓ In Medicare beneficiaries

Long-Term Services and Supports Progress Report

Jane Tilly, Dr.PH
Office of Supportive and Caregiver Services
Administration on Aging/
Administration for Community Living

2013 Recommendation Discussion

»» LTSS
Research
Clinical Care

Long Term Services and Supports Subcommittee

Recommendations

States should assure robust, dementia-capable LTSS systems

- ▶ Every state should identify a state lead entity
- ▶ The system should include a full array of LTSS that are culturally and linguistically competent and evidence-informed or evidenced-based
- ▶ Services include – outreach; early detection; diagnostic; care and estate planning; treatment (medical, psychiatric, pharmacological and social/cognitive interventions e.g., memory classes); care/treatment advocacy (e.g., medication management, benefits counseling and patient navigation); early stage support services; social support services (such as **adult day services** etc) supportive housing; safety services; hospital and community based end-of-life and palliative care

LTSS System (con't)

- ▶ Services for families and caregivers include – outreach; advocacy; disease and self-care education; caregiver assessment; support groups; supports for long distance caregivers; dementia care management; legal and financial (**including family care tax relief policies and benefits counseling**) services; respite services; and supportive workplace family care policies.

LTSS System (con't)

- ▶ Providers should utilize innovative gap filling/financing strategies.
- ▶ CMS should provide guidance to all states about how to add adult day services as a state optional service under Medicaid.
- ▶ Services should encourage development and provide LTSS linkages to state, local; and private supportive housing resources.
- ▶ Services should encourage development and implementation of dementia-capable transportation services.
- ▶ Public and private payments for services should reflect a living wage and recognize any special training for dementia capable service providers

HHS should fund support to a state lead entity in every state and territory

- ▶ The lead entity will be responsible for: facilitating development of dementia capable systems, coordinating public and private resources and programs; building capacity for epidemiology; evaluating programs and improving quality; maximizing the positive impact of services for people with AD and their caregivers; reducing duplication; coordinating public awareness efforts; and assuring that evidenced-based, high quality services are available.
- ▶ HHS should identify an appropriate office or operating division to manage funds for the program supporting the state lead entities and convene representatives of state lead entities regularly.

State Lead Entity (con't)

- ▶ HHS should develop standards for state lead entities that should be met as a condition of funding. Understanding that states are organized differently, standards should be flexible enough to accommodate various entities as lead.
- ▶ Governors should be enlisted to designate the lead entity for their state to assure appropriate authority.
- ▶ States should draft (or update) a state plan to address AD, in concert with the National Plan.
- ▶ HHS should fully fund the costs of cognitive impairment and caregiver surveillance through the Behavioral Risk Factor Surveillance System in every state.

LTSS Research

- ▶ **HHS should engage all relevant federal agencies to include research on LTSS that addresses dementia capability in their research agendas**

Key information about AD should be in all curricula.

- ▶ State education/health agencies, regional accrediting bodies, and professional organizations should require that current information about AD be included as a condition of approval of any curriculum or course of study leading to relevant provider licensure or certification.
- ▶ Appropriate organizations should require that current information about AD be included in all relevant continuing education activity and all relevant state recertification programs.
- ▶ State, local, and private sector first responders, health and human service personnel, and others who serve the public should receive appropriate information and training regarding AD and the early warning signs of possible cognitive impairment to assure they can effectively perform their work.

Adequate training and compensation should be ensured.

- ▶ State/Local/Private authorities should require that paraprofessional caregivers receive at least 10 hours of dementia specific training from a reliable source.
- ▶ States should enact policies that ensure that their hours and pay reflect a fair and living wage because many of these workers are working multiple shifts at below subsistence wages, often with few benefits,.
- ▶ Public and private sector compensation should reflect the completion of a prescribed training program.

Medicare coverage should be redesigned to encourage appropriate diagnosis and care planning for people with AD and their caregivers

- ▶ Congress should pass legislation to create Medicare coverage for a package of services that covers the clinical diagnosis of AD as well as care planning for the individual and their caregivers.
- ▶ This Medicare coverage should include care planning with a family caregiver even if the individual with the disease is not present.
- ▶ Medicare reimbursement for this package of services should require that physicians and other healthcare providers should be required to document the AD diagnosis and any associated services provided in the individual's medical record.
- ▶ The Health Resources and Services Administration (HRSA) and CMS should clarify and disseminate information to providers about the procedures under Health Insurance Portability and Accountability Act with regard to sharing medical information with caregivers related to dementia, prognosis, and care planning.

LTSS systems should refer people to a healthcare provider for diagnosis

- ▶ Whenever a person exhibits symptoms of cognitive decline, providers should consider a diagnosis using the 2011 guidelines.
- ▶ The state lead entity should assure that this recommendation is included in any assessment for eligibility for LTSS.
- ▶ Federal agencies should assure that appropriate training resources are available to health care providers on the use of the guidelines.

Diagnosis should include individual and family in advance care planning (health, legal, estate, and financial).

- ▶ Health and LTSS providers should include advance care planning in the health and LTSS care plan.
- ▶ Health and LTSS providers should have ready access to information for referral of people diagnosed with AD and their family to community resources for financial and estate planning.
- ▶ The state lead entity should assure that an inventory of community resources is maintained through appropriate state, local, and private resources.

HHS should assure that systems improve chronic disease treatment for people with AD.

- ▶ People with AD often have other (multiple) chronic conditions. Treatment options for persons with AD are limited and prognosis is negatively affected when individuals have acute flare-ups related to their other conditions or complications, (e.g., stroke, chronic obstructive pulmonary disease, coronary heart disease).
- ▶ Providers should incorporate training regarding the impact of AD on care for comorbid conditions in existing pre-service and in-service training curricula.
- ▶ Professional organizations should develop tools and guidance for clinicians and social service professionals.
- ▶ Professional organizations should develop tools for caregivers, which help them with manage multiple chronic conditions. These tools should link to the HHS Framework to Address Multiple Chronic Conditions.

HHS should develop quality measures for the comprehensive care and treatment of individuals with AD.

- ▶ AHRQ – in consultation with the National Quality Forum, the Institute of Medicine, and various stakeholders – should develop quality care measures and indicators for diagnosis, treatment, and care of individuals with AD.
- ▶ Over time, these quality measures and indicators should cover care in the full array of medical and LTSS settings; care coordination and transitions among settings.
- ▶ The Centers for Medicare and Medicaid Services (CMS) should implement demonstration projects to study the application of dementia quality care measures and indicators as they are developed.
- ▶ CMS should implement policies for Medicare and Medicaid to embed the quality measures and indicators in the health and LTSS care system.

Practice recommendations for care in every setting should be embedded in surveillance and QI systems.

- ▶ Stakeholders should develop or update consensus practice recommendations for the full array of LTSS settings.
- ▶ These guidelines should be widely disseminated and embedded in all federal and state surveillance and quality improvement systems.
- ▶ Practice recommendations should include the appropriate management of AD and common co-morbid physical and behavioral health conditions.

HHS should form a blue ribbon panel of experts

- ▶ **The Panel should recommend one or more models of palliative care for people with advanced dementia, including eligibility criteria and financing mechanisms, and provide grants through CMMI to implement and evaluate the models.**

Recommendations for end-of-life or palliative care should be part of CMS surveillance and QI systems.

- ▶ Because at this time AD is a terminal illness marked by diminishing capacity, providers should discuss and document use of palliative care and desires regarding end-of-life care as early as practical in the disease process.
- ▶ Federal and state surveillance and quality improvement systems should all include measures of whether this communication has taken place in a meaningful way

HHS should provide grants through CMS CMMI for medical home pilot projects

- ▶ Within one year, CMMI should provide grants for medical home pilot projects specifically targeted at Medicare beneficiaries with AD.
- ▶ Within one year, CMMI should provide grants for medical home pilot projects specifically targeted at dual eligible individuals (those seniors eligible for both Medicare and Medicaid) with AD.
- ▶ CMS should incorporate those projects that prove successful into the Medicare and Medicaid programs.

CMMI should implement a new round of grants targeting preventable ED visits, hospitalizations, and LOS for individuals with AD.

- ▶ HHS, states, and the private sector should work together to develop and evaluate methods of improving hospital care, care coordination, and transitions of care for people with AD, including training approaches and proposed quality measures.
- ▶ Within one year of formation of this partnership, CMMI should create a specific grant round focused exclusively on pilot projects and demonstrations to reduce emergency department visits, preventable hospitalizations and length of hospital stays among individuals with AD.
- ▶ Funded projects should include at least one project that targets individuals from diverse communities.

HHS and states should partner to assure access for specific populations including younger people, people with intellectual disabilities, such as Down syndrome, and racial and ethnic minorities who are at increased risk of acquiring AD.

- ▶ HHS and state lead entities should work with providers to assure that supports are tailored for caregivers/family members of specific populations with AD.
- ▶ All guidelines and quality improvement efforts should include specific populations.
- ▶ Congress should amend the Older Americans Act Title III to make these services available to those with younger-onset AD.

Recommended use of Federal Funds (\$10.5 million) currently proposed for AoA

- ▶ HHS (AoA) should use the \$10.5 million for state grants to seed the development of state action plans that maximize use of public and private resources to support dementia capable LTSS.
- ▶ Governors should designate the state lead entity and commit to sharing publicly a state plan with recommendations for action.
- ▶ State agencies and relevant partners should be included in the state action plan.
- ▶ Legislation enacting this program should require matching funds so as to expand program impact.
- ▶ This program should be expanded in future years with additional resources.
- ▶ Estimated funds necessary to fully fund all states' action plans = \$85 million.

Funding for the ADSSP should be restored to \$13.4 million.

- ▶ ADSSP supports evidenced-based and innovative practices that assist people with AD and their caregivers in the community.
- ▶ HHS, state lead entities and partners can use the lessons learned from this program to spread the availability of valuable services and should develop a long-range plan to convert ADSSP from a demonstration program to a program that provides widely-available services based on the findings from the demonstrations.

Fully fund caregiver support under AoA

- ▶ AoA currently has the National Family Caregiver Support Program, a component of which can be expanded to better meet the needs of caregivers of individuals with AD.
- ▶ These improvements may result in mitigation of other system costs.
- ▶ This program is currently dramatically underfunded and therefore unable to meet the needs of this growing population of caregivers.
- ▶ Fully funding this program can enhance other related efforts to improve quality of life for people with AD and their caregivers.
- ▶ We recommend that program funding be doubled to move toward full funding.

HHS, states, and providers should assure that caregiver physical health/ behavioral health risk is assessed and addressed regularly.

- ▶ The health and well-being of a caregiver has a direct impact on the health and quality of life of a person with AD.
- ▶ Whenever a caregiver accompanies a person with AD to a health care appointment; emergency department visit; or hospitalization, the attending health care provider should ask if the caregiver is well for the purpose of information and referral to services, if needed.
- ▶ HHS should explore HIT and surveillance systems to determine whether caregiver risk assessment is occurring.
- ▶ Appropriate federal, state, and private sector organizations should assure that the importance of this action is incorporated into training of health and LTSS providers and incorporated into education messages for the public.

- ▶ The Office of the National Coordinator for Health Information Technology, in partnership with the private sector, should work to assure that development of health information technology includes tools that assist caregivers of persons with AD. Tools could assist caregivers by: helping them organize the care they provide, educating them about dementia and multiple chronic conditions, and providing tools to help them maintain their own mental and physical health.
- ▶ Caregivers should have access to reminder tools; communication methods among caregivers; home monitoring tools; and enhanced decision supports that help instill confidence and reduce isolation.

HHS should launch a nationwide public awareness campaign to increase awareness and to promote early detection of AD.

- ▶ HHS should coordinate a public awareness campaign with relevant federal agencies and other stakeholders in a public-private partnership.
- ▶ HRSA should partner with CDC and other HHS agencies, as well as professional groups to launch a parallel awareness campaign targeted at physicians and other health care professionals.
- ▶ Both campaigns should include promotion of Medicare's Annual Wellness Visit as a vehicle for health care professionals and patients to talk about memory problems and cognitive function.
- ▶ The campaigns should include specific efforts in diverse communities and populations, including younger-onset individuals and persons with intellectual disabilities.
- ▶ The campaigns should involve appropriate state, county, and local organizations, including public health departments, and encourage them to launch public awareness and early detection campaigns of their own.

Research Subcommittee Recommendations

Themes of original research recommendations

- Commit resources with accountability
- Accelerate basic and translational research toward development of effective treatments
- Maximizing private investment to develop treatments and improve disease monitoring technology
- Meaningfully coordinate with global partners

Recommendation 1

We support and applaud the goal of the National Plan -- to prevent and effectively treat Alzheimer's Disease by 2025.

- ▶ Development of interim milestones, such as a significant disease-modifying or substantially-enhanced symptom-mitigating behavioral or pharmacologic intervention by 2020.
- ▶ New investment in research must reflect a critical balance between basic research and the urgency treatment discovery.

Notes on Recommendation 1

- ▶ Appendix 4 of the Plan provides implementation milestones for each of the Goals and Actions
- ▶ However the implementation plan is not detailed enough to know if FACA recommendations are addressed, including 2020 interim goals.
- ▶ Explicit timelines, such as one that works backward from 2025 to sketch out therapy discovery and approval timelines are not incorporated into the implementation plan.

Recommendation 2

There is an urgent need for annual federal research funding to be increased to the level needed to fund a strategic research plan and to achieve the breakthroughs required to meet the 2025 goal. Initial estimates of that level are \$2 billion per year but may be more. That investment would be applied to Alzheimer's research initiatives spanning basic, translational and clinical research.

Notes on Recommendation 2

- ▶ Introduction of the Plan mentions Obama Administration's investment of \$50 million in new Alzheimer's disease research funding in fiscal year 2012 and \$80 million in new Alzheimer's disease research funding in fiscal year 2013
- ▶ This could represent the initial stages of a ramp-up but the urgency of getting to \$2 billion is unchanged

Recommendation 3

We recommend that HHS develop, execute and regularly update a strategic research plan and priorities to accelerate breakthroughs in AD research.

Notes on Recommendation 3

- ▶ Actions 1.A.1 and 1.A.5 focus on development of the strategic research plan.
- ▶ Very productive meetings have occurred, and NIA RFAs are being developed as a result of the recommendations
- ▶ A comprehensive strategy of applying these recommendations across public and private funding sources has not been developed
- ▶ The synchronization and coordination between the contents of the National Plan and a research plan is not explicit.

Recommendation 4

To address disparities, we recommend that clinical research studies and activities aimed at translation of research findings into medical practice and to the public include specific targets for outreach to specific populations by racial/ethnic group, sex, and socioeconomic status, as well as to populations at high risk for AD (e.g., people with Down Syndrome).

Notes on Recommendation 4

- ▶ Outreach to ethnic groups is mentioned in Strategy 1B and specifically addressed in 1.B.4
- ▶ However the detailed recommendations re: leveraging existing resources and engaging private entities are not included, and the emphasis on "translation of research findings" to diverse populations is not explicit in the Plan.
- ▶ Down syndrome and intellectual disability populations are not specifically mentioned within Goal 1.

Recommendation 5

We recommend that HHS, in partnership with the research community and industry, take steps to accelerate public access to new therapeutic interventions by compressing the current average time in the process of identification of therapeutic targets, validation of those targets, development of behavioral and pharmacologic interventions, testing of efficacy and safety, and regulatory review.

Notes on Recommendation 5

- ▶ There is significant overlap between the broad intent of the recommendation and the Plan (Action 1.E.1.)
- ▶ Many details included in the recommendation are relevant to the implementation plan but are not included
- ▶ We are considering consolidation of recommendations 5,6,7 & 8

Recommendation 6

We recommend that the Secretary, in consultation with academic researchers, not-for-profit Alzheimer's organizations, and the private sector, including sponsors of investigational diagnostic and therapy trials, by year-end 2012 identify and prioritize the action steps needed to reduce the time for moving therapies from target identification and validation through clinical development, regulatory review, market approval, and reimbursement determinations.

Notes on Recommendation 6

- ▶ Action 1.E.1 focuses on shortening timeline
- ▶ Action 1.E.2 focuses on public private partnerships for dissemination, translation, and implementation
- ▶ The role of PPPs in enhancing scientific innovation and discovery, or progress in shortening the regulatory process is not uniquely emphasized in the plan
- ▶ Consolidation and revisions of recommendations may result in one for shortening timeline and one focusing on the broad role of PPPs in research

Recommendation 7

We recommend that the Secretary examine and include as part of her annual report to Congress and the Advisory Council:

- ▶ How the HHS will reduce barriers and accelerate development of new therapies
- ▶ Immediate steps the HHS will take to address any identified drug development barriers,
- ▶ Additional authorities or other legislative action that may be needed to accelerate development of therapies and diagnostics
- ▶ Immediate steps to shorten time from market approval to coverage decision

Notes on Recommendation 7

- ▶ Action 1.E.1 focuses on compressing timeline of therapy development
- ▶ The implementation plan does not currently include the steps detailed in this recommendation

Recommendation 8

We recommend that the FDA review and periodically report to the Advisory Council recommendations to further accelerate FDA review processes without compromising current standards of safety and efficacy.

Notes on Recommendation 8

- ▶ Action 1.E.1 will identify ways to compress the time between target identification and release of pharmacological treatments
- ▶ The implementation plan for 1.E.1 identifies the FDA as a partner agency in identification of places where timeline could be shortened
- ▶ The implementation plan indicates that Sept 2012 is the goal date for this feedback to be offered to the Advisory Council

Recommendation 9

We recommend that the HHS Secretary develop a continuing process by which research priorities aimed at accelerating the delivery of effective treatments would be set, including input from scientific experts. In our view, a joint NIH and industry working group should be established, which can serve as an opportunity to create a true partnership between government and industry to inform research priorities.

Notes on Recommendation 9

- ▶ Action 1.A.2 is to solicit public and private input on AD research priorities, and the specific example is to issue an RFI to invite public and private input
- ▶ No specifics are offered on how this will be an ongoing process in plan development
- ▶ Multiple ongoing PPP initiatives are moving forward on this recommendation and thus specifics could be integrated in future versions of the plan

Recommendation 10

We recommend that HHS develop accurate and relevant metrics for assessing the impact of Alzheimer's on the U.S. economy.

Notes on Recommendation 10

- ▶ There is general overlap between this recommendation and Goal 5, which discusses metrics
- ▶ However measurement of economic impact of AD, or the rationale for doing so, is not specifically discussed in Goal 5 or elsewhere in the Plan

Recommendation 11

We recommend that HHS commit to an effort to maximize private investment in the development of treatments and improvements in disease monitoring technology by identifying policies that would encourage private industry to invest aggressively in disease-modifying interventions, to support technologies that improve our ability to detect the disease as early as possible, and monitor the disease accurately so that the effectiveness of interventions can be tested.

Notes on Recommendation 11

- ▶ Goal 1.D generally mentions private partners
- ▶ However the 1.D actions items appear to focus on Global partners only
- ▶ There is tremendous detail in terms of implementation in this recommendation that is not carried through to the Plan
- ▶ There is overlap between this recommendation and other FACA recommendations that mention the importance of private partners
- ▶ We might want to clarify this recommendation or integrate it with other PPP focus throughout.

Recommendation 34

We recommend that the Administration expand and enhance meaningful coordination with global partners and move forward to establish a Global Alzheimer's Action Plan to respond to the global scope of the problem.

Notes on Recommendation 34

- ▶ Strategy 1.D calls for coordination of research internationally, via inventory and outreach to international partners
- ▶ Global partners participated in the May 2012 meeting, met with HHS at the Vancouver AAIC, and a number of bilateral efforts have begun
- ▶ Early spring 2013 is a target date for an international meeting
- ▶ There is no explicit mention of a Global AD Plan.
- ▶ A single high level official whose responsibility it is to foster international cooperation has not been identified
- ▶ There has been no coordinated discussion internationally of regulatory hurdles.

Recommendation 35

We recommend that the Administration designate specific Offices and officials within the White House and the Office of the Secretary of HHS with responsibility and accountability for effective implementation of, and timely, transparent reporting on, all aspects of the implementation of this National Alzheimer's Plan, including responsibility for issuing statutorily required reports to Congress on behalf of the Secretary, reports to the Advisory Council, and other reports as warranted.

Notes on Recommendation 35

- ▶ The implementation strategy designates specific offices responsible for Action Items in the Plan.
- ▶ No separate office in the White House is mentioned in the Plan.
- ▶ Unaddressed aspects of this item include detail about metrics, milestones, implementation steps, and accountability.

Clinical Care Subcommittee

Recommendations

Workforce

- ▶ **A prevention or cure is not imminent**
 - Incentives to work in geriatrics– lets get specific
 - Loan forgiveness (not just for underserved areas)
 - Title VII and VII of Public Health Services Act
 - Enhance current workforce to be dementia “capable”
 - HRSA and partners to collaborate on health professions curricula – disseminate broadly.
 - National programs targeted to various health professionals.
 - Even medical sub-specialties – i.e. Dementia in ER settings
 - Certification/licensure – varied across states.

Detection and Diagnosis

- ▶ **Await the workgroup rec’s on detection tool**
- ▶ **Still favor Medicare comprehensive coverage for diagnosis/care planning visit.**
 - Enhanced service with enhanced reimbursement
 - Care planning with patient/caregivers
 - Reimburse even if patient not present for some of visit
 - Include legal, financial, advance care planning
 - Enhanced documentation in medical record (required)
 - Still need some clarification on HIPAA and dementia

ACA – Medical Home

- ▶ Current plan suggests sub-group analysis of existing programs, but not new program.
- ▶ CMMI should consider specific grant to **Medical Home for patients with dementia.**
 - This might be more efficient and effective than including patients with dementia in a mixed medical home model.

Multiple chronic conditions

- ▶ **Alzheimer's Disease as multiplier**
 - Makes management of other diseases more difficult and costly
 - Very little available through Medicare to support providers and patients with this challenge
 - Two CMMI funded projects in our first plan
 - Very little research on best practices or cost effective management – despite large growth in this population
 - Little specific to dementia in area of transitions/re-hospitalizations despite new data (Callahan)

Care throughout the stages

- ▶ **Many policy considerations that could make significant differences for families dealing with Alzheimer's/other dementias**
 - Medicare benefit earlier than 65 w/diagnosis
 - Extend Medicare homebound status for people with moderate dementia so that home supports can be strengthened – visiting aides, nursing, etc.
 - Tax credits for out of pocket costs for family caregivers

Advanced dementia

- ▶ **High Priority – poorly coordinated care that is very costly. Given rapidly growing numbers this area becomes an urgent need in the next plan.**
 - Improvements in care can make a difference quickly.
 - Many areas already dovetail with current CMS initiatives.
 - Management of infections – antibiotic resistance
 - Feeding and nutrition issues
 - Transitional care and hospitalizations
 - Communication and identification of goals of care

Advanced dementia

- ▶ CMS and other partners to co-sponsor a blue ribbon panel of experts/researchers in this area.
 - Consideration of where research can identify quality innovations in care delivery or coordination quickly.
 - What policy incentives can promote best practices in advanced dementia care in all settings?
 - Address the disconnect between Medicare and Medicaid programs for this vulnerable group.

Awareness

- ▶ Parallel campaign for health professionals – emphasizing the importance of early detection and skill development as we manage more people with dementia.
- ▶ Concern that an awareness campaign should provide information about where to go for specific needs...
 - Highlight annual Medicare wellness visit

Public Comments

napa@hhs.gov

