

# 2022 Research Recommendations

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July 25, 2022

## 2022 NAPA Research Themes

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Coordination among agencies to accelerate translation of research into clinical practice.

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Increase involvement of people with AD/ADRD in clinical research.

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Increase funding and resources for research and implementation science.

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Representation, diversity, access, and health equity in AD/ADRD clinical trials.

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## RECOMMENDATION 1

Increase synergies among all federal agencies involved in the National Plan to facilitate faster and more comprehensive translation of research into clinical practice of evidence-based advancements and approved diagnostic, treatment, and care paradigms to improve outcomes for people with dementia.

- A. Federal agencies responsive to NAPA should work together to identify areas with the opportunity for translation of research to clinical practice to occur more rapidly.
- a. Examples include:
- i. *Coordination in the review of clinical studies* that demonstrate effectiveness of treatments and tests to determine the standards of clinical utility and approval for access and payment.
  - ii. Collaboration by the agencies responsible for approval for access and payment on an *agreed set of measures, analytic tools, and standards of clinical benefit* for functional, clinical, cognitive, patient reported, and other outcomes applicable for review is needed to guide clinical studies.
  - iii. NAPA agencies should also evaluate opportunities to better implement research supported strategies to improve the health and care of AD/ADRD and *report recommendations to NAPA and the appropriate government bodies to make needed changes to implement improvements.*

## RECOMMENDATION 1 (cont'd)

Increase synergies among all federal agencies involved in the National Plan to facilitate faster and more comprehensive translation of research into clinical practice of evidence-based advancements and approved diagnostic, treatment, and care paradigms to improve outcomes for people with dementia.

- b. Examples of coordinated programs include:
- i. *Diagnostic tests for Alzheimer's disease* and other neurodegenerative diseases by CSF, PET scans, or blood tests which can provide accurate diagnosis.
  - ii. *Therapeutic development of drugs and interventions* which can improve clinical outcomes and impact the progression or risk of the disease.
- c. *Increase cross-agency interaction* to plan strategic cross-agency responsiveness to relevant NIH Summit recommendations and other translational priorities for AD/ADRD, and address barriers to doing so.

One suggested venue is to *establish an annual meeting of NAPA agencies associated with current NIH summits* to occur before or after with alignment and implementation of research goals with NAPA agency goals.

Implementation to be supported with NAPA organizers, including ASPE, with *increased resources and authority to track the progress and milestones* of prior recommendations with the authority to prioritize, organize, implement, and *follow up on cross-agency recommendations.*

## RECOMMENDATION 2

By the end of 2022, NAPA federal agencies should investigate and propose successful models for increasing involvement of people with AD/ADRD in clinical research studies, including trials. The proposal should evaluate how clinical care can be synergized with research participation to accelerate scientific advancements that can be quickly translated into clinical practice. The goal should be for all people with AD/ADRD to be offered opportunities to participate in research.

- A. The *potential impact of FDA approval of anti-amyloid therapies, including aducanumab, should be studied to understand their impact on research efforts and the goals of NAPA* to implement effective treatments and prevention by 2025.
  - A. Areas of study with high-impact implications include how *approval and access to disease modifying drugs will impact research participation in clinical trials, clinical trial design, review and approval of drug use, payer coverage, and implementation of treatments.*
- B. The rapid pace of translating Covid-19 research findings into clinical practice highlight opportunities to improve the coordination and translation of research discoveries into care impact for people with AD/ADRD and unpaid caregivers. Increased funding and resources from Congress are needed for *NAPA federal agencies to review and implement relevant Covid-19 approaches as a model for novel AD/ADRD approaches to accelerate translation of clinical trials, review and approval of demonstrated effective tests and treatments, and clinical care implementation.*
- C. The newly created *ARPA-H should play a major role in the translation and demonstration of scientific breakthroughs in the diagnosis, treatment, and management of dementias.*

## RECOMMENDATION 3

A top priority remains the urgent need for Congress to continue to increase annual federal research and implementation science funding (by NIH and other agencies) sufficient to meet NAPA goals across biomedical, clinical, long-term services and supports, and public health settings.

High-priority areas of research include:

- A. Fundamental biological processes and basic disease mechanisms of AD/ADRD (e.g., young and late onset sporadic AD, familial AD, individuals with Down syndrome).
- B. Dementias with clinical diagnoses other than AD and mixed/multiple etiology dementias (e.g., primary tauopathies, alpha-synuclein, TDP-43, vascular, etc.).
- C. Early detection of cognitive decline and precursors of dementia at an individual level, *identification of the pathology(s) causing a person's trouble, and development and testing of treatments targeted appropriately at the biologic underpinnings* in a given individual.
- D. Models of dementia care and support and the testing of innovative payment models (potentially funded by CMS/CMMI, private foundations, etc.).
- E. Translational technologies for diagnostics and therapeutics, including diagnostic testing and CNS drug delivery.
- F. Prevention and risk reduction of cognitive decline and dementia, as discussed in more detail by the risk reduction subcommittee.

#### **RECOMMENDATION 4**

Representation and diversity in AD/ADRD clinical trials should continue to be increased to address health equity and representation in research.

Potential strategies include:

- A. Leveraging models of community-based recruitment.
- B. Integrating into primary care systems with recruitment of clinical patients.
- C. Scaling up of funding to enable research to develop and grow the necessary infrastructures.
- D. Targeted RFAs.
- E. Requirements by NIH, CMS, and other funding agencies for trial and observational study enrollment, and including PPI panels inclusive of those living with dementia and unpaid caregivers representative of these diverse targets.

#### **RECOMMENDATION 5**

Research into implementation of dementia care to provide best care models should continue to be increased.

- A. Examples include evidence-based interventions such as medication management, care support, clinical care team management, exercise, diet, and activity. Diagnostic strategy implementation from primary care through specialty centers should also continue to be studied.
- B. Timely and accurate diagnostic and prognostic information should be provided for people with ADRD and caregivers (as appropriate) using recent scientific developments in biomarkers such as PET, CSF, and blood-based diagnostic tests. Access to diagnostic evaluations should include all communities.

## **RECOMMENDATION 6**

An understudied area that should be prioritized is the impact of stigma related to dementia on health-seeking behaviors to improve access to health services.

- A. Current work has focused on stigma attached to race/ethnicity, sex and gender, and socioeconomic status. A greater understanding of these and other factors, including the stigma on dementia itself, is needed to understand and resolve patient, family, caregiver, medical provider, and societal effects of stigma on access to care, diagnosis and treatment, and support systems. This research may help identify why payers have not supported newer diagnostic evaluations and what is needed to provide accurate diagnosis of AD and related dementias.

## **RECOMMENDATION 7**

A cross-cutting recommendation across all NAPA subcommittees is to increase research into neurological effects of Covid-19 and development of emergency preparedness programs for the safety and wellness of older adults and people with ADRD.

- A. Encourage longitudinal study into the effects of Covid-19 on the brain, inclusive of neuroinflammation, and their long-term impact on diagnostic, treatment, and support systems.
  - A. Research should have an emphasis on inclusion of diverse populations, taking into consideration race and ethnicity, rural and urban areas, and representative geographical areas across the US and globally if possible.
- B. Encourage research into the development of community-based programs designed in a proactive and preemptive manner to provide for the safety and wellness of those living with AD/ADRD and their care partners. Examples include research into effectiveness of dementia training for first responders and integration of dementia-trained professionals as part of mental health response teams.

# Research Subcommittee Membership

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- Randall Bateman (Chair)
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- Helen Bundy Medsger
- Adrienne Mims
- Joanne Pike
- Rhonda Williams

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- Sarah Fontaine, CDMRP/DOD
- Richard Hodes, NIA
- Melinda Kelley, NIA
- Helen Lamont, ASPE
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- Shari Ling, CMS

# 2022 Clinical Care Recommendations

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July 25, 2022

## Themes

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Inclusivity – Coordinated and integrated system of screening, assessment, diagnostic services, and care plan reaching into and available to all segments of our society, and incorporating caregivers in clinical care.

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Equity – Key consideration across recommendations

- \* Social determinants of health
  - \* Equitable access
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Evidence-based practice – Best available research, clinical experience, patient’s lived experience and preferences (patient’s and family’s) to improve quality of care, quality of life and health outcomes.

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Accountability – Development and implementation of national standards of clinical care and evaluation methods.

### RECOMMENDATION 1

**Educate the public about the importance of risk reduction, early detection and accurate diagnosis of Alzheimer’s disease and related dementia care models for person-centered and family-centered care, resource access and utilization.**

- A. NIH and CMS (and State Departments of Health) should offer guidance on assessing and diagnosing adults with suspected AD/ADRD who present with life-long neurotypical conditions, are not primary English language speakers, or come from cultural or ethnic groups.
- B. NIH and ACL should develop and distribute dementia educational materials in varied languages and within context of cultural or ethnic target groups and that destigmatize perceptions of AD/ADRD among these groups.
- C. The HHS operating divisions, the U.S. Department of Veterans Affairs (VA), and the U.S. Department of Defense (DoD) should educate the public at the national, state, and community levels about the benefits of risk reduction, early detection and diagnosis of AD/ADRD.
- D. By 2025, hospitals and healthcare provider practices serving people living with AD/ADRD should have procedures to identify cognitive impairment, integrate its management into the care plan, and provide timely diagnosis.
- E. The NIA should identify protocols and instruments as well as issue guidelines for the screening, assessment, and diagnosis of adults with cultural, language, and disability backgrounds differing from the general population.

## **RECOMMENDATION 2**

**Expand and enhance the current and future clinical care workforce through training, continuing education, mandated standards, and remuneration to better address the needs of persons living with AD/ADRD and their families/caregivers.**

- A. Federal agencies and others should continue to offer and support current and future workforce education to improve workforce members' abilities to work with persons of all ages, living with AD/ADRD and their family caregivers, including those in diverse communities.
- B. Workforce education programs should include recognizing and addressing risk factors, early signs and symptoms (within a person- and family-centered cultural context), early detection, diagnosis, treatment, plan of care, offering and providing counseling to persons living with AD/ADRD and their family members and caregivers, and connecting them to local services and resources for continuity of care at all stages.
- C. NIH and CMS (and State Departments of Health) should offer guidance on assessing and diagnosing adults with suspected AD/ADRD who present with life-long neurotypical conditions, are not primary English language speakers, or come from cultural or ethnic groups with beliefs and norms at variance to the main population of a specific area.
- D. Policy maker discussions should include stakeholders' input about payment models based on clinical care recommendations, research, etc.
- E. Develop, test and implement integrated person-centered and family-centered models of care for people living with dementia, especially in primary care settings.
- F. Expansion of training across all clinical disciplines including recertification maintenance of state licensure.
- G. Federal programs and others should report on the number of workforce members trained per year, and this reporting should be considered in updates to the National Plan.

## **RECOMMENDATION 3**

**Using the best available evidence, stakeholders should reach consensus on guidance for best practices for diagnosis, management and integration of family caregivers into the care team. For developing comprehensive multi-stage care of persons with AD/ADRD, consideration should include the uniqueness of different populations.**

- A. There should be current best practices for comprehensive care of AD/ADRD at all disease stages, informed by evidence, so that persons living with AD/ADRD (including racial and ethnic communities that are disproportionately affected), caregivers, health systems, and payers have similar understanding regarding diagnosis, treatment, and/or services and supports, and research opportunities.
- B. An effort, supported by the federal government, should be undertaken to identify clinical and care best practice models that can be easily documented and made available for use throughout the nation.
- C. The effort should involve a range of experts and representatives from diverse interests, professional backgrounds, and populations impacted by AD/ADRD.



#### **RECOMMENDATION 4**

**Encourage further development, evaluation, and implementation of person-centered and family-centered health care models for AD/ADRD that align performance measures and payment models. These models should incorporate the lived experience of care of persons living with AD/ADRD of all ages and their caregivers, always considering diversity.**

- A. Federal agencies (CMS, VA, HHS), states, and non-governmental payers for health care services should increase the use of value-based care for persons living with AD/ADRD.
- B. Initiatives delivering value-based programs should rely on definitions of value outlined by CMS and others.
- C. Initiatives to assess value should be informed by evidence, and new research should be conducted to study how models of care improve health outcomes, including the effective management of comorbidities.
- D. Initiatives to assess value should rely on a framework such as the CMS Meaningful Measures initiative, and apply such a framework specifically for persons living with known AD/ADRD or cognitive impairment and their family members and caregivers.
- E. States and other payers States and other payers (Medicare, Medicaid) should increase attention to cost-effective HCBS, which support person-centered care and self-determination for persons living with AD/ADRD and their caregivers and consider means to reimburse these providers for their services to patients.

#### **RECOMMENDATION 5**

**To assure health equity, remove any barriers for the receipt of, and payment for, clinical and care services, and long-term services and supports, for adults living with dementia who are under the age of 65.**

- A. The National Plan should address the following issues that are barriers to clinical care and community-based long-term services for younger individuals living with AD/ADRD.
  - 1. The Older Americans Act requires recipients to be age 60 or older to receive covered services. Congress should amend the Older Americans Act to provide services for persons under age 60 living with dementias.
  - 2. This barrier is a two-year waiting period for younger individuals living with AD/ADRD who have been deemed eligible for Social Security Disability Insurance (SSDI) to have access to Medicare. This is a barrier to clinical care for younger people with dementia. Congress should eliminate this waiting period.

## **RECOMMENDATION 6**

**Accelerate efforts to promote healthy aging, reduce risk factors for AD/ADRD and intervene early in clinical care.**

- A. Federal partners** should take measures to ensure that the health care workforce understand the risk factors for dementia and promote brain health maintenance and dementia risk reduction actions in people of all ages.
- B. Health systems** should implement a comprehensive set of actions to assess and reduce dementia risk, delay the onset of dementia, and improve early intervention for their patients - ensuring equitable reach and impact for historically marginalized populations. Expand system dementia-capability and utilize CDC resources to increase health and social service providers' awareness of brain health as a serious public health concern using existing and future resources.
- C. Clinicians** should identify opportunities to reduce the risk of mild cognitive impairment and dementia. Access education for the clinical care and patients on promoting brain health. Use quality measures specifically related to dementia risk reduction. Learn existing health system and home and community-based resources. Participate in dementia specific continuing education. Disseminate dementia risk reduction practices on co-occurring chronic conditions and dementias. Expand the availability and reach of dementia education and health promotion resources in health settings. Increase awareness of substance use disorder (SUD) and its impact on older adults and AD/ADRD.

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- Joan Weiss, HRSA

# 2022 LTSS Recommendations

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July 25, 2022

## Themes

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Decrease disparities, increase equity and expand access to an utilization of LTSS

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Improve coordination of clinical care with HCBS

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Provide high quality, person and family-centered LTSS

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Develop a dementia-capable workforce

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Address behavioral & psychological symptoms of ADRD across care settings

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Improve and expand LTSS emergency preparedness

## **RECOMMENDATION 1**

Expand access to and utilization of affordable HCBS, particularly for people living with ADRD who are marginalized, historically underserved, or disproportionately affected by dementia.

- A. Expand access through Medicaid
- B. Expand access through Medicare
- C. Expand, fully fund, and promote LTSS programs beyond Medicaid
- D. Protect the financial security of people living with ADRD and their caregivers

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Decrease disparities, increase equity and expand access to an utilization of LTSS

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- D. Protect the financial security of people living with ADRD and their caregivers

## Risk Reduction Subcommittee Membership

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