Research Subcommittee Recommendations

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1

Research Subcommittee Members

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- Adrienne Mims
- Joanne Pike
- Yakeel T. Quiroz-Gaviria
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- Arlene Bierman - AHRQ
- Ellen Blackwell - CMS
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- Rebecca Ferrell - NSF
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- Richard Hodes – NIA
- Amy Kelley - NIH
- Melinda Kelley - NIA
- Walter Koroshetz - NINDS
- Helen Lamont - ASPE
- Shari Ling - CMS
- Maria-Theresa Okafor - ASPE
- Courtney Wallin - NIH

2

Recommendation 1:

Increase federal research funds to meet NAPA aims.

A. Understanding fundamental biological processes and basic disease mechanisms of AD/ADRD.

B. Studying dementias with clinical diagnoses other than AD, mixed/multiple etiology dementias, assessments and outcomes of importance to patients and families, and translation across different neurodegenerative diseases and purposes.

C. Early detection of cognitive decline and precursors of dementia at an individual level, identification of pathology(s), and development and use of person-centered treatments.

D. Recently developed amyloid therapies including optimal duration of treatment, characteristics of patients and groups who benefit, and medical system delivery.

E. Developing and evaluating implementation of models of dementia care and support and the testing of innovative payment models (beyond CMS models); encourage uptake efforts through state public health and aging services departments.

3

Recommendation 1 (continued):

Increase federal research funds to meet NAPA aims.

F. Workforce and systems capacity needs in clinical care and research staffing across and within diverse geographical regions of the U.S. Funding and resources should be allocated to AHRQ for this purpose.

G. Further development of translation for diagnostics and therapeutics and the implementation process in clinical settings.

H. Evidence for and methods of improving prevention and risk reduction of cognitive decline and dementia.

I. Neurological effects of COVID-19 in older adults and PLWD.

J. Causes, relationships, and risk reduction of delirium in PLWD.

K. Implementation of a dementia portfolio that enables the translation and demonstration of scientific breakthroughs in the diagnosis, treatment, and management of dementias and efficient translation of evidence to patient care by the newly created Advanced Research Projects Agency for Health.

4

Recommendation 2:

Address critical scientific and clinical questions in the implementation of the first generation of disease-modifying treatments.

Research is needed to determine:

A. How best to identify persons who would benefit from anti-amyloid therapy and ensure equitable access and ability to participate in therapy, especially marginalized populations.

B. Which persons with cognitive decline and evidence of amyloid deposition in the brain but did not fit criteria of the successful clinical trials, may also benefit from anti-amyloid therapy.

C. The infrastructure needed to appropriately identify, treat, and monitor persons treated with new therapeutic agents, beginning with anti-amyloid therapy.

D. The causes of side effects and adverse reactions in persons treated with anti-amyloid therapy and how to best monitor and manage these.

5

Recommendation 2 (continued):

Address critical scientific and clinical questions in the implementation of the first generation of disease-modifying treatments.

Research is needed to determine (continued):

E. Early, accurate, and minimally invasive detection of the disease followed by differential diagnosis testing options to identify persons who may benefit from receiving anti-amyloid therapy.

F. Whether anti-amyloid treatment of cognitively normal persons identified as high risk for future cognitive decline based on blood or PET biomarkers can help prevent or delay the onset of cognitive impairment.

G. How to manage persons treated with anti-amyloid therapy over longer time periods including patients who progress to dementia, the effects of multiple co-morbidities and medications, optimal treatment duration, and cessation criteria.

H. Novel approaches for prevention and early detection of the disease, as well as the risks and benefits of disease-modifying treatments for those with Down syndrome and other forms of AD.

6

Recommendation 3:

Implement research of active dementia care models to compare effectiveness.

Research is needed to:

A. Study the effectiveness of diagnostic strategy implementation on the continuum of primary care to specialty centers. Determine how to provide timely and accurate diagnostic and prognostic information for PLWD using recent scientific developments in biomarkers. Identify barriers to implementing dementia care models in primary care and strategies to support primary care and other providers in this role.

B. Develop, implement, and improve person-centered models of care for PLWD and their caregivers. Interventions should continue to be studied.

C. Determine how to integrate medical interventions within medical systems and to measure their effects on quality of life, function, and other outcomes.

D. Develop and implement care models for PLWD not being adequately served by current models (e.g., those under age 65, with IDD and dementia, unhoused, or incarcerated). Determine the efficacy of current models in these populations, and capacity to implement effective programs. Funding and resources should be allocated to AHRQ to contribute to this.

7

Recommendation 4:

To address health equity, underrepresentation of diverse populations in research, in AD/ADRD clinical trials should be increased.

A. Leveraging community engagement models to promote diverse recruitment and participation, as well as primary care, scaling up of research funding, targeted Request for Applications, government requirements for trial and observational study enrollment, publication requirements, and including patient and public involvement of PLWD and unpaid caregivers.

B. Prioritize inclusion and representation of diverse populations in public/private clinical trials, fund research into the science of recruitment and retention, and set milestones for engagement and inclusion of underrepresented populations.
   1. Support initiatives that promote health equity and address systemic barriers to participation in clinical trials.
   2. Ensure clinical trials are accessible to diverse participants, including non-English speakers and individuals with disabilities.
   3. Analyze trial outcomes by demographic variables to understand potential disparities and inform future research and clinical trials.

C. Prioritize study of the impact of stigma related to dementia on health-seeking behaviors to improve access to health services.
   1. More research focused on stigma attached to sociodemographic and cultural factors is needed to understand and resolve effects of stigma on access to care, diagnosis and treatment, outcomes, and support systems.

8

Recommendation 5:

Accelerate translation from scientific discovery to health impact.

A. Congress should reauthorize NAPA for another ten years. Update NAPA's first goal to treat and prevent AD/ADRD by 2035.

B. Congress should appropriate funds for NAPA organizers, including ASPE, to have increased resources and authority to accomplish:
   1. For FY2025, fund and appoint at least 1 FTE for federal coordinator(s) with the authority to prioritize, organize, implement, and follow up on cross-stakeholder recommendations.
   2. Track the progress and milestones of prior NAPA recommendations.
   3. Assist NAPA Council and its Chair in determining the level of resources for NAPA to track and convey recommendations optimally.

C. Independent annual funding for NAPA goals and management are needed to accomplish the NAPA aims. This should include funding to support:
   1. Management of the top-level NAPA roadmap.
   2. Implementation and support for NAPA related meetings, including travel costs and time and effort of required attendees.
   3. Staff to provide support for NAPA leadership to accomplish aims.
   4. Provide mechanisms to engage multiple stakeholders beyond federal agencies.

9

Recommendation 6:

Implement scientific and evidence-based evaluations of factors for decision-making.

A. Perform implementation science research to determine safety, utilization, and outcomes from ongoing treatments while accounting for potential added burden on patients, caregivers, and healthcare systems that would impact health of patients with AD/ADRD.
   1. The Patient and Public Involvement framework should be integrated throughout the research cycle. PLWD and their caregivers should be active members of the research team and recruiting individuals from previously underrepresented populations should be high priority.

B. NAPA federal agencies should investigate successful models for increasing involvement of PLWD in clinical research studies, including trials.
   1. For example, the Peer Reviewed Alzheimer's Research Program of the DoD CDMRP requires all clinical research applications to involve people with lived experience in meaningful and equitable ways throughout the research cycle and involve them as equal partners in peer review.

C. Study how access to disease-modifying drugs affect research participation in clinical trials, clinical trial design, review and approval of drug use, payment, coverage, and implementation of treatments.

10