Research Subcommittee Recommendations

July 29, 2019

Research Themes:

- Robust biomedical and holistic strategy.
- Sufficient resources.
- Silos minimized.
- Optimal infrastructure and research climate.
- An inclusive role for the dementia community.
- Global leadership role.
- Broad dissemination.
- Commitment to quality.
- Continuous and objective process improvement.

RECOMMENDATION 1: The 2019 National Plan should continue to provide a robust, comprehensive, collaborative and transformative scientific road map for achieving the goal of preventing, effectively treating, and providing effective care and services for AD/ADRD by 2025.

a. A road map for accomplishing the primary goal of the Plan should include input from experts in the field through recurring research summits on AD/ADRD, and care and services.

    - Cross-agency collaboration between federal agencies on the annual summits is essential to advance progress. Representatives of all federal agencies involved in the NAPA plan should attend the summits and coordinate efforts.

    - Federal agencies should support global efforts to address issues of research, care and services, and workforce development in order to facilitate international collaboration and minimize silos of knowledge.

b. Recommendations from these summits and the research community should be re-evaluated each year and translated into milestones by federal agencies involved in NAPA and relevant partners.

c. Federal agencies should monitor progress of research milestones as described in the summit recommendations.

RECOMMENDATION 2: A top priority remains the urgent need for Congress to continue to increase annual federal research funding sufficient to meet all the 2025 goals, across biomedical, clinical, LTSS and public health.

a. The annual professional judgment budget required by the Alzheimer's Accountability Act and prepared by the NIH should reflect the science-driven funding needs for the budget year to enable investigators to reach the 2025 goals of the plan.

    - This investment would be applied to AD/ADRD research initiatives spanning basic, translational, clinical, care and services research.

b. All federal agencies should submit AD/ADRD research funding awards and amounts annually to the NIH International Alzheimer's Disease Research Portfolio (IADRP).

RECOMMENDATION 3: Emphasis should be given to the standardization of terminology across the spectrum of cognition in neurocognitive disorders by all agencies involved in the National Plan, to reduce ambiguity over confusing or overlapping terms, reduce stigma associated with AD/ADRD, and improve public awareness of AD/ADRD and access to relevant resources and services.

a. Convene a working group of thought leaders to develop an inclusive process that will define the challenges of today's dementia-related nomenclature and propose strategies to develop improved, standardized terminology for use across different audiences without sacrificing scientific accuracy.

    - As any change to dementia nomenclature can have wide-ranging impact across research, regulatory issues, clinical care, reimbursement issues and public health efforts, Dementia stakeholder organizations should assist this initiative through administrative and meeting planning support and funding.

b. Updated terminology should improve public awareness of cognitive impairment and diseases causing dementia, be culturally sensitive, be free of stigma and negative stereotypes, provide clarity between disease etiologies and clinical syndromes, address both staging of disease progression and stages of functional abilities from preclinical stage through advanced dementia, and improve identification of caregivers and also address the training needs of the workforce providing AD/ADRD care and services.

c. The issue of dementia nomenclature should be considered in the planning of any annual summits.

RECOMMENDATION 4: A major area of emphasis by all federal agencies involved in the National Plan should be the enhancement of recruitment efforts for research involving those with, or at risk of developing, AD/ADRD.

a. Emphasis should be placed by federal and non-governmental agencies, academia, service providers and community partners on the enhancement of diversity and inclusiveness in these efforts to improve health outcomes for communities affected by health disparities.

b. NIH should advance innovative recruitment efforts to increase recruitment and retention in randomized controlled clinical trials. (see recommendation on clinical care)

c. All federal and non-federal agencies funding AD/ADRD research should require documentation of recruitment goals in applications for clinical research; incentives should also be in place for meeting those goals.

RECOMMENDATION 5: Federal agencies should develop a strategy and infrastructure to increase ethical and open sharing of, access to, and utilization of research data, with a continued emphasis on ethics, in collaboration with academia, biotech and information system industries. This strategy should accelerate the pace of scientific discovery in AD/ADRD science by addressing a comprehensive range of issues including cross-sector data sharing practices and policies, data harmonization and interoperability, and the training of data scientists in AD/ADRD research.

a. Special emphasis is needed on data sharing of completed biomarker studies and drug and non-drug clinical trials, including industry-sponsored trials. Patient advocacy and regulatory changes may be required.

RECOMMENDATION 6: All federal and non-governmental agencies funding AD/ADRD research, along with PCORI, academia and industry, should establish the engagement of the AD/ADRD community as a standard practice in both participating in setting national research priorities for AD/ADRD and throughout all stages of clinical research and care, and services and support research.

a. NIH, federal agencies involved in NAPA, and PCORI should develop evidence-base for optimal methods, assessment and impact of engaging persons with AD/ADRD and their care partners, leveraging international expertise as needed.

b. NIH should establish funding methods to support participant/caregiver engagement in all AD/ADRD clinical research, including leveraging ongoing guidance to the field on methods of research engagement from PCORI, through its reauthorization by Congress.

c. Through participant/caregiver engagement, NIH, other federal agencies and PCORI should identify meaningful person and caregiver-centered outcomes and validated measures for AD/ADRD by disease etiology.

d. Enhance methodologies to effectively engage persons living with AD/ADRD, families and caregivers in research on decision making and care planning.

e. NIH, other agencies involved in NAPA, and PCORI should establish methods for researchers and other stakeholders to identify how research stakeholder engagement is integrated into study planning, conduct and reporting, as well as dissemination and implementation.

RECOMMENDATION 7: To expand access to brain tissue needed for AD/ADRD research purposes, NIH should explore gaps in tissue availability for research, and review and refine the current infrastructure at the NIH NeuroBioBank and Alzheimer's Disease Research Centers (ADRCs) to Fill these gaps. NIH should consider the value of widening outreach to accept brain donations from clinically well-characterized individuals, such as those receiving clinical care at dementia research sites like ADRCs and Udall Centers.

a. Collaborations should be considered that leverage existing NIH-funded brain banks and AD/ADRD research programs, with continuing attention on consent issues, harmonizing protocols and data sharing practices.