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

Summer 2024 Meeting



August 2, 2024

U.S. Department of Health and Human Services
Materials available at: http://tinyurl.com/NAPAmeetings



OFFICE OF BEHAVIORAL HEALTH, DISABILITY, AND AGING POLICY

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Federal Updates

- Administration for Community Living (ACL)
- Agency for Healthcare Research and Quality (AHRQ)
- Office of the Assistant Secretary for Planning and Evaluation (ASPE)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Indian Health Service (IHS)
- National Institutes of Health (NIH)





OFFICE OF BEHAVIORAL HEALTH, DISABILITY, AND AGING POLICY

Administration for Community Living

August 5, 2024

Erin Long, MSW

Team Lead, Alzheimer's & Dementia Programs
Administration on Aging
Administration for Community Living



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ACL Alzheimer's Disease Programs Initiative (ADPI) Center for Dementia Respite Innovation (Funded October 2023)

- Alzheimer's Association, University of Minnesota School of Public Health and USAging;
- July 2024 announced award of more than \$4 million in grants;
- 21 community-based service providers to increase the availability of quality dementiaspecific respite care.
- https://www.alz.org/news/2024/dementia-respite-innovation-grants-awarded
- https://www.alz.org/professionals/professional-providers/center-for-dementia-respite-innovation

National Alzheimer's and Dementia Resource Center UPCOMING WEBINAR

Dementia Friendly Clark County Nevada: What Happens in Vegas Affects the World

Monday, August 12, 2024 | 3:00-4:00 PM ET

Dementia Friendly Clark County is a grassroots initiative in the Las Vegas Valley with a focus on strengthening local communities to become more respectful, educated, supportive, and inclusive of people living with dementia and care partners. Attendees will learn how their impact isn't confined to the local community by training hotels and the international airport, they extend their reach globally.

Register here: August 12 NADRC Webinar Registration

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National Alzheimer's and Dementia Resource Center UPCOMING WEBINAR

Cognitive Stimulation Therapy Programs for People Living with Dementia

Tuesday, August 27, 2024 | 2:00-3:00 PM ET

Learn from two ADPI grantees that are expanding their services by providing this small-group, evidenced-based intervention. Through virtual and in-person sessions, participants strengthen their retained cognitive abilities and decrease depressive symptoms, while gaining confidence and social connection and improving their well-being. This therapy program is geared for a wide range of people living with ADRD.

Register here: NADRC August 27 Webinar Registration

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National Alzheimer's and Dementia Resource Center Recent Webinars

- Unique Approaches to Support Brain Health and Reduce Risk through Education, Exercise,
 Diet, and Art (May 22, 2024) Participants learned about ACL's Brain Health & Aging
 resources, and the We Program in Puerto Rico, designed for their high-risk population
 combining education, exercise, cooking workshops, arts, and horticulture into a fun and
 social opportunity for people to learn about brain health and dementia risk reduction
 techniques
- Building Dementia Awareness in Tribal Communities through Interactive Programming:
 Implementing the Virtual Dementia Tour (VDT) (June 25, 2024). Attendees learned about
 the VDT as a powerful way to build understanding and open the door to greater
 conversation and education about dementia within Tribal Communities. Presenters
 discussed their experiences using the Virtual Dementia tour and its impact within the
 Oneida Nation.

The recording of al ACL NADRC webinars are posted at https://nadrc.acl.gov/home

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New Resources at National Alzheimer's and Dementia Resource Center

(https://nadrc.acl.gov/home)

- UPDATED Grantee Implemented Evidence-Based and Evidence Informed Dementia Interventions (NADRC)
- IDEA! Workbooks in English, Japanese and Korean (CA)
- Empowering Caregivers: A Culture of Caring Program Guide for Companies (AZ)
- Transitions Hospital and Home Coach Training (KY)
- Dementia Friendly First Responder Online Training Program (AL)
- Supportive Care for Dementia Implementation Manual 12 training videos (AZ)
- Caregiver Stress Prevention Bundle Manual (IN)



Resource Highlight Great Lakes Intertribal Council Together Strong Dementia

Dementia



A Day in the Life; A Tribal Dementi Story



In Our Own Voices: Tribal Elder's thoughts and words about Dementia

- https://www.youtube.com/@GLITCTogetherStrongDementia
- https://www.glitc.org/programs/aging-disability/resources/

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Thank you!

Erin Long, MSW
Team Lead, Alzheimer's Disease Programs Initiative (ADPI)
Office of Supportive and Caregiver Services
Administration on Aging
Administration for Community Living

Email: Erin.Long@acl.hhs.gov

AHRQ's Strategic Plan: Advancing Health System Transformation to Optimize Health, Functional Status, and Well-being among Older Adults



Vision: All people receive high-quality person-centered care based in primary care that optimizes health, functional status, and well-being well-being as they age, and advances health equity.

- Support health system transformation by funding research to develop, implement, evaluate, and scale person-centered models of care to optimize physical and mental health, functional status, and well-being among older adults for individuals and populations.
- Disseminate and implement evidence to improve health outcomes and experience of care
 of older adults.
- Support training and mentoring of health services researchers with expertise in improving care delivery for older adults.
- Expand and create synergies across AHRQ's portfolio to support health system
 transformation to improve care quality such that it is timely, equitably distributed, safe, and
 effective, leading to better health and well-being for older adults and widely communicate
 that aging is a priority of AHRQ to internal and external audiences.
- Develop strong federal, health system, public health, and private sector partnerships to transform health care delivery to meet the needs of an aging population.

https://www.ahrq.gov/priority-populations/publications/aging-well.html

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NEW: Special Emphasis Notice (SEN) Improving Care for Older Adults



Health Services Research to Improve Care Delivery, Access, Quality, Equity, and Health Outcomes for Older Adults

https://grants.nih.gov/grants/guide/notice-files/NOT-HS-24-013.html

- This SEN conveys AHRQ's interest in supporting health services
 research to conduct research that will address questions related to the
 development, implementation, evaluation, and scale of person-centered
 models of care to optimize physical and mental health, functional
 status, and the well-being among older adults.
- This SEN builds on AHRQ's prior work, including the <u>Optimizing Health and Function as We Age Roundtable Report</u>, <u>Research Agenda for Transforming Care for People with Multiple Chronic Conditions</u>, and the <u>Multiple Chronic Conditions</u>, and the <u>Multiple Chronic Conditions</u> e-careplan. It also supports AHRQ's ongoing commitment to the inclusion of priority populations in health services research (<u>About Priority Populations</u> | Agency for Healthcare Research and Quality (ahrg.gov).

AHRQ's Healthcare Extension Service



- Goals
 - ► Accelerate the dissemination and implementation of PCOR evidence into practice
 - ▶ Reduce healthcare disparities among Medicaid beneficiaries, uninsured, and medically underserved
- Notice of Information to Publish Notice of Funding Opportunity (NOFO)
 Announcements for AHRQ's Healthcare Extension Service to Accelerate Implementation of Patient-Centered Outcome Research Evidence into Practice
 - ▶ Published June 6, highlighted 3 components
 - State-based Healthcare Cooperatives
 - A National Coordinating Center
 - A National Evaluation Center

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Health System Transformation and Aging Well The "Sweet Spot" Policy Payment Sweet Spot Evidence Generation

MCC eCare Plan FHIR Implementation Guide (IG)



The <u>HL7® MCC eCare Plan FHIR Implementation Guide (IG)</u> defines FHIR R4 profiles, structures, extensions, transactions, and value sets needed to represent, query for, and exchange Care Plan information to support care planning for people with multiple chronic conditions (MCC).

The IG supports the following use cases:

- Generate and update comprehensive e-care plan in clinical setting.
- Expose (Share) e-care plan to clinical care team, patient, or caregiver.
- 3. Identify care team members.



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Person-Centered Care Planning Initiative



Partner Engagement and Learning Community

- Gather knowledge about the current state of person-centered care planning in practice, including person-centered care planning models in use across diverse health systems, practices, and settings; scale of existing models; implementation barriers and facilitators; and feasible solutions to implementation barriers;
- Identify innovative, feasible models of person-centered care planning that hold promise for further development, testing, dissemination, and implementation;
- Identify innovative digital solutions that have been leveraged as tools to support and facilitate the success of implementing person centered care planning in practice;
- Identify key organizational, policy, payment, technology, cost, and resource requirements for implementing person-centered care planning across diverse health systems, practices, and settings; and
- Identify key research priorities, strategies, recommendations, and next steps to advance AHRQ's mission of disseminating and implementing person-centered care planning as routine and integral practice in the care of persons with MCC.

Defining Person-Centered Care



"Person-centered care" means that individuals' values and preferences are elicited and, once expressed, guide all aspects of their health care, supporting their realistic health and life goals. Person-centered care is achieved through a dynamic relationship among individuals, others who are important to them, and all relevant providers. This collaboration informs decision-making to the extent that the individual desires.

"Person-Centered Care: A Definition and Essential Elements" The American Geriatrics Society Expert Panel on Person-Centered Care, December 2015 https://www.ncbi.nlm.nih.gov/pubmed/28626262

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Person-Centered Care Planning for People Living With Multiple Chronic Conditions (PCCP4P)



- Contract through AHRQ's ACTION IV Network to OHSU
- Technical Expert Panel
- Partner's Roundtable includes leadership from health systems, state health agencies, payers, professional societies, federal partners
- Learning Community includes innovators, implementers, frontline workers, researchers
- Summit Spring 2025

August 2024 Updates

Helen Lamont, Ph.D.

Director, Division of Disability & Aging Policy



U.S. Department of Health and Human Services



OFFICE OF BEHAVIORAL HEALTH, DISABILITY, AND AGING POLICY

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Recent ASPE Briefs

- Changes in Ownership of Skilled Nursing Facilities from 2016 to 2021: Variations by Size, Occupancy Rate, Penalty Amount, and Type of Ownership
 - Examined ownership data and identified facilities more likely to experience ownership changes and varying NH ownership structures and transactions potentially influencing quality of care delivered to vulnerable residents.
 Facilities that were medium-sized, had low occupancy rates, or had incurred more fines, were more likely to experience a change of ownership
- Medicaid Home and Community-Based Services Section 1915(c) Waiver Policy Flexibilities During the COVID-19
 Public Health Emergency: State Agency, Provider, and Consumer Experiences
 - Interviewed state agencies and HCBS consumer and provider groups from nine states about their experiences with the selection, implementation, evaluation, and continuation of Appendix K policy flexibilities adopted during the COVID-19 public health emergency (PHE). State agencies relied on prior experiences, feedback from HCBS provider and consumer groups, and priorities around health and safety concerns, and addressing workforce shortages. Some challenges with implementation included uncertainty around duration of flexibilities, accessing and interpreting flexibility guidance, limited state administrative infrastructure, and provider payment uncertainty/delays.





OFFICE OF BEHAVIORAL HEALTH, DISABILITY, AND AGING POLICY

U.S. Centers for Disease Control and Prevention



August 2024 Updates

Alisha A. Etheredge, MS, MPH Lead, Alzheimer's Disease Program Team

National Center for Chronic Disease Prevention and Health Promotion

Division of Population Health, Healthy Aging Branch

Presented August 5, 2024 at the National Alzheimer's Project Act (NAPA) Advisory Council

Quarterly Meeting

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NEW PUBLICATION

Scheduled for release at 10 am ET on August 8, 2024





ETHNOGERIATRICS AND SPECIAL POPULATIONS

Journal of the American Geriatrics Society

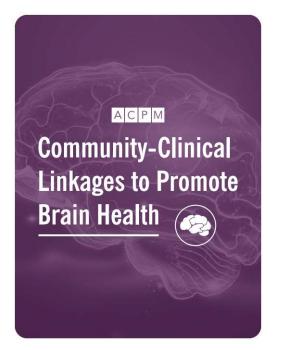
Alzheimer's disease and related dementia diagnoses among American Indian and Alaska Native adults aged ≥45 years, Indian Health Service System, 2016–2020

Andria Apostolou PhD, MPH¹ | Jordan L. Kennedy MSPH² |

Marissa K. Person MSPH² | Eva M. J. Jackson MPH³ | Bruce Finke MD⁴ |

Lisa C. McGuire PhD⁵ | Kevin A. Matthews PhD⁵ DOI: 10.1111/jgs.19058

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NEW Toolkit: Community-Clinical Linkages to Promote Brain Health

Brain-Health-Kit-v10.cdr (acpm.org)

- Designed for preventive medicine providers to implement and inform their practice around improving brain health within health systems.
- This tool aims to activate preventive medicine physicians and educate patients on ADRD, reduce risk factors related to dementia, and improve the brain health and cognitive functions of populations by leveraging clinical-community linkages through an equity-centered approach.

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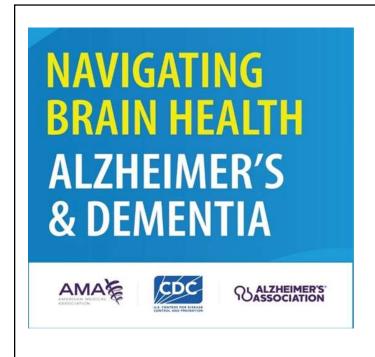
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NEW Launch of ACPM Brain Health Courses

- Improving Brain Health: A
 Practical Review of Dementia
 Risk Reduction Strategies
- Heart Healthy is Brain Healthy:
 Cognitive Decline and
 Dementia Risk Reduction
 through Blood Pressure Control

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Webinar Series:
Navigating Brain
Health with AMA,
CDC, and Alzheimer's
Association

Access the recordings and claim CME!

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HBI Road Map Strategists: Opportunity for Local Health Departments

Applications now open!

- National peer cohort focused on implementing HBI Road Map actions in communities
- Local health departments (LHDs) receives funding, technical assistance, and peer support
- Up to 10 LHDs will be selected for a 9-month program
- Establishes a Road Map Strategist within the LHD, a public health professional focus on building dementia expertise and changing system
- Next cohort launches January 2025







Applications due September 26, 2024

Learn more at the Alzheimer's Association Submittable page

Alzheimer's: A Public Health Issue

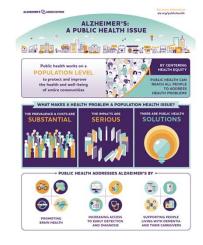
New Infographic Resource

Quick explainer of:

- Public health
- Alzheimer's and dementia as public health issues

Find it at alz.org/publichealth
→ Public Health and Alzheimer's

Direct Link Download





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HBI Road Map for American Indian and Alaska Native Peoples Update

- Development of the next edition of the Road Map for Indian Country — renamed the Healthy Brain Initiative: Road Map for American Indian and Alaska Native Peoples — is underway.
- Leadership committee and Federal Liaison review of a full draft is complete
- <u>Progress Update</u> available on the Alzheimer's Association <u>website</u>
- New Road Map will be released in November 2024



SDOH Resources – 2 more Webinars and Infographics

- Register for the series and share the flyer and opportunity with your health department contacts
- Participants will be able to:
 - Identify the relationship between SDOH and dementia risk.
 - Understand modifiable risk factors and their impact on dementia risk reduction.
 - Learn strategies from State and Local Health Department experts on integrating dementia risk into broader public health agendas.
 - Engage in a discussion during the Q&A portion of the event.
- SDOH Infographics related to dementia risk reduction now available



Register today <u>bit.ly/PHCOEwebinar!</u>

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NEW Risk Factor Videos

- Alzheimer's Association Public Health
 Center of Excellence on Dementia Risk
 Reduction recently released new videos
 on modifiable risk factors for cognitive
 decline, featuring experts from the
 Association and Rush Alzheimer's Disease
 Center.
- Presenters shared scientific evidence on:
 - Diet and Nutrition
 - Cognitive Engagement
 - Mild Traumatic Brain Injury



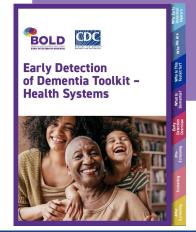
Watch and share the video series at bit.ly/3U795JK

Resources

NYUBOLDCenter@nyulangone.org https://bolddementiadetection.org/

Toolkit for Health Systems

https://bolddementiadetection.org/resources/#toolki



Access the toolkit here:



Webinars

Engagement and Reach

- Four webinars have attracted a total of 1,399 unique registrants
- Of the 1,399 unique registrants, 1,224 (87%)
 were not previously in our listserv,
 demonstrating the success of these
 webinars in attracting new audiences
- Created a new web resource, 'Webinar
 Excerpts' for our audience to catch up on
 the key take-homes from our panelists in
 our short (<5 minute) clips</p>

Visit the Webinars page to learn more and watch past webinars and short clips! https://bolddementiadetection.org/webinars/



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Webinar Highlight

Linking Statewide Dementia Screening to Diagnostic Social Services



NYUBOLDCenter@nyulangone.org https://bolddementiadetection.org/

Highlighted takeaway from the panelists:

Aging and Disability Resource Centers (ADRCs) can be the front line of cognitive screening and they can be supported through continuing education from memory clinic programs. Memory clinics can improve the cognitive screening process by helping ADRCs collect key information in addition to the objective screening measures, as well as providing community members with an understanding of the memory clinic evaluation process.



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Virtual Roundtable Series

Building a public health community of practice

- Roundtables highlight different public health approaches to building the state dementia caregiving infrastructure, one state at a time
- Interactive sessions, designed for peer-learning and knowledge sharing

Last episode...



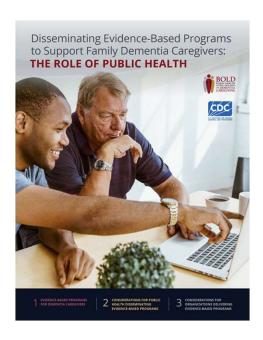
Upcoming...



Register at bit.ly/SuccessfulPublicHealthApproaches-NewYork

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NEW Toolkit Launched July 24, 2024



Watch recordings at:

https://youtube.com/playlist?list=PL3Jsff3FCIMSOysHj HRsbPKjXV_EAgpjY&si=5ZH4mO_3fymMlzIF

Coming Soon...



Webinars

Successful Public Health Approaches in Dementia Caregiving Roundtable series

- · August 14, 2024 New York State
- · October (day TBD) Colorado

Building Our Largest Dementia (BOLD) Public Health Programs & Geriatric Workforce Enhancement Programs – Coordinating Center (GWEP-CC) Webinar

· September 24, 2024

Publications

Integrating Community Health Workers in Public Health Dementia Efforts

Regional Differences in Dementia Caregiver Health Outcomes: the Need for Local-Level Data to Tailor Caregiver Programs and Supports in their Communities

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Serving Black and Latino Communities

Activities since April 2024:

- ✓ Nurse Fellowship 12 Black and Latino nurses completed 5 mandatory workshops on brain health/AD knowledge and how to be a brain health ambassador; in the process of conducting AD prevention-focused community conversations with community members and peers – will be completed by September 2024
- Empowering FQHCs who Serve High-Need Populations with Primary Care Prevention Information:
 - Partnered with BOLD Grant Recipient
 Mississippi Dept of Public Health and
 delivered webinar tailored for MS
 healthcare providers and social workers,
 especially those in FQHCs, on brain health
 prevention strategies. Social workers were
 able to get Continuing Education credits
 for attendance. Approx: 24 leaders in
 attendance
- ✓ Digital ad campaign launched Launched 2024 ad campaign directly linking people to a page with culturally-tailored AD information. Previous ad campaigns have reached a total of 2.3 million Latino & African American people.
- Spanish language materials created/released
 - Translated the CDC co-branded, evidencebased "Practical Guide on Communicating Brain Health Messages in Black and Latino Communities" and accompanying social media toolkit – available here
 - All Nurse Fellow Community Conversation materials (pre- and post-tests; template presentations)
 - All digital ad campaign assets (ads and landing pages) were created concurrently in English & Spanish
- Engaging in Thought Leadership with Nurses
 - Worked with HBI Component B partners, IA² and HealthMatters, to lead discussion on intersectional identities in AD with current and alumni Brain Health Equity Fellows

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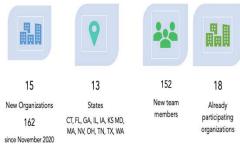
UsAgainstAlzheimer's

HealthMatters for People with IDD



- Supporting 162 organizations across the U.S. to implement the Virtual HealthMatters Program and provide 6 Pillars of Brain Health among People with IDD and their Supports.
- Developing Fact Sheets for Brain Health and Dementia Care from Listening Circles in collaboration with International Association for Indigenous Aging (IA2)/HealthMatters Program.
- Co-presented with UsAgainstAlzheimer's and IA2 to discuss common cultural values, barriers and facilitators; dispel myths; and provide tools/resources for nurses providing dementia care.
- Provided 6 Pillars for Brain Health: Promoting Health Equity for People with Intellectual and Developmental Disabilities training to Americorp Members working with The Arc US in July.

Virtual Coach HealthMatters™ Program Impact



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NTG Updates

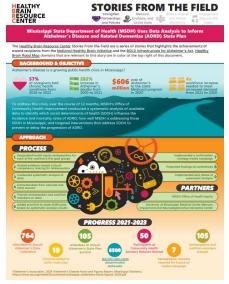


NTG funded with Special Olympics Inclusive Health Initiative Project, "Changing Thinking! A National Initiative to Enhance Access to Critical Health Care and Supports for Adults with Intellectual and Developmental Disabilities and Dementia." September 2024 through June 2025.

- Implementing CMS Guiding an Improved Dementia Experience (GUIDE) Model to support adults with IDD and their caregivers affected by dementia
- Incorporate Gerontological Society of America (GSA) 2024 publication, <u>Addressing Brain Health in Adults With Intellectual Disabilities and Developmental Disabilities: A Companion to the KAER Toolkit for Primary Care Providers</u>. The KAER Toolkit provides resources for <u>Kickstarting</u> brain health needs, <u>Assessing</u> cognitive impairment, <u>Evaluating</u> for dementia, and <u>Referring</u> to community resources.
- Operationalize the 2024 seminal report on autism, dementia, brain health titled "Autism, aging, and dementia: A consensus report of the Autism/Dementia Work Group of the 2nd International Summit on Intellectual Disabilities and Dementia."

NEW Stories from the Field Posted on CDC's HBRC Website

- Healthy Brain Resource Center (HBRC)
 Stories from the Field are a series of stories that highlight the work of our BOLD and HBI grant recipients
- Newest story highlights the <u>Mississippi BOLD public health</u> <u>program</u> and their work to address social determinants of health that influence the incidence and mortality rates of ADRD



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Advancing Dementia Care: Introducing Virginia Dementia Patient Registry



With a pressing need for specialized care and accurate data on dementia prevalence, the <u>Virginia Department of Health (VDH)</u> embarked on a groundbreaking initiative. Supported by CDC funding, VDH awarded four mini-grants to enhance community education, caregiver training, and the development of a state-of-the-art dementia registry: the Virginia Dementia Patient Registry.

This registry, one of only four in the country, provides valuable insights into dementia prevalence among different groups. By leveraging this information, social and medical services can be tailored to meet the specific needs of individuals living with dementia. These projects are made possible by the "Building Our Largest Dementia Public Health Programs to Address Alzheimer's Disease and Related Dementias" award.

Alisha Etheredge, MS, MPH aetheredge@cdc.gov

http://www.cdc.gov/aging







For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 cdc.gov Follow us on X (Twitter) @CDCgov & @CDCEnvironment

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U. S. Centers for Disease Control and Prevention.

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Donanemab (Kisunla) Indication: Treatment of Alzheimer's Disease

Teresa Buracchio, MD Director, Office of Neuroscience Center for Drug Evaluation and Research



Donanemab

 Donanemab (Kisunla) received traditional approval on July 2, 2024, based on results from a Phase 3 randomized, controlled clinical trial (TRAILBLAZER-ALZ2) and a Phase 2 (TRAILBLAZER-ALZ)

www.fda.gov 43

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TRAILBLAZER-ALZ2 (AACI)

- An 18-month (76-week) Phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group study in patients with mild cognitive impairment due to Alzheimer's disease (AD) or mild AD dementia
- Randomization to placebo (n=874) or donanemab (n=853) in a 1:1 ratio
- Dosing Regimen: Donanemab 700 mg administered as an IV infusion every 4 weeks for the first 3 doses, then 1400 mg every 4 weeks for up to 72 weeks. Donanemab treatment was switched to placebo based on amyloid PET levels measured at Week 24, Week 52, and Week 76
- Statistically significant treatment effects were demonstrated on primary and secondary endpoints
 - Change from baseline in iADRS compared to placebo in the low/medium tau population (3.25 [-35%], p<0.001) and the
 overall population (2.92 [-22%], p<0.001) at Week 76
 - Components of iADRS: Change from baseline in ADAS-Cog 13 (-1.52 [-32%], p<0.001) and ADCS-iADL (1.83 [-40%], p<0.001) and the overall population: ADAS-Cog 13 (-1.33 [-20%], p<0.001) and ADCS-iADL (1.70 [-28%], p<0.001)
 - Change from baseline in CDR-SB compared to placebo in the low/medium tau population (-0.67 [-36%], p<0.001) and the overall population (-0.70 [-29%], p<0.001) at Week 76
 - Change from baseline on brain amyloid plaque levels as measured by PET(-86.4 Centiloids, p<0.0001)

www.fda.gov 44



TRAILBLAZER-ALZ (AACG)

- A 76-week Phase 2 multicenter, randomized, double-blind, placebo-controlled, parallel-group study in patients with mild cognitive impairment due to Alzheimer's disease (AD) or mild AD dementia (similar design to AACI)
- 257 subjects randomized: 131 in the donanemab arm and 126 in the placebo arm
- Donanemab treatment demonstrated a statistically significant reduction in brain amyloid plaque from baseline to Week 76 compared to placebo (-85.1 Centiloid, p<0.001)
- The primary efficacy endpoint analysis, change from baseline in iADRS at Week 76, demonstrated a statistically significant treatment effect in the donanemab treatment arm compared to placebo (3.20 [-32%], p=0.042)
- Favorable numerical results for secondary clinical endpoints were observed and were consistent with observations in Study AACI

www.fda.gov 45

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Safety in the Phase 3 study

- The most common adverse events in the Phase 3 study were ARIA, headache, and infusionrelated reaction
- ARIA (-E/-H) was observed in 36% (307/853) of subjects treated with donanemab, compared to 14 % (122/874) of subjects on placebo
 - ARIA-E was observed in 24% (201/853) and ARIA-H was observed in 31% (263/853) of patients treated with donanemab
 - Symptomatic ARIA occurred in 6% (52/853) of patients treated with donanemab
 - There were 3 deaths associated with ARIA and 1 of those deaths was caused by intracerebral hemorrhage
- The incidence of ARIA was higher in ApoE ϵ 4 homozygotes (55% on donanemab vs. 22% on placebo) than in heterozygotes (36% on donanemab vs 13% on placebo) and noncarriers (25% on donanemab vs 12% on placebo)

www.fda.gov 46



Prescribing Information

- **Indication:** KISUNLA is indicated for the treatment of Alzheimer's disease. Treatment with KISUNLA should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.
- Dosing: Consider stopping dosing with KISUNLA based on reduction of amyloid plaques to minimal levels on amyloid PET imaging. In Study 1, dosing was stopped based on a reduction of amyloid levels below predefined thresholds on PET imaging

www.fda.gov 47

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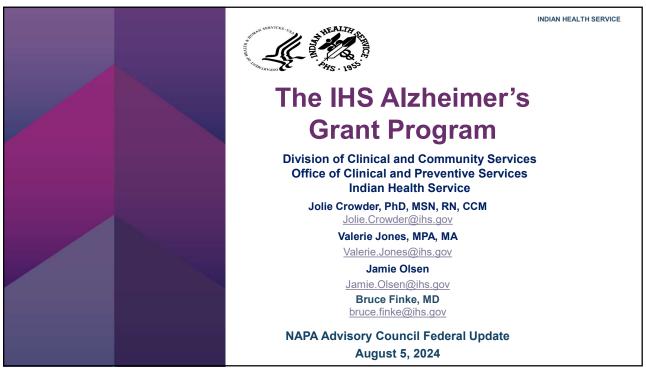


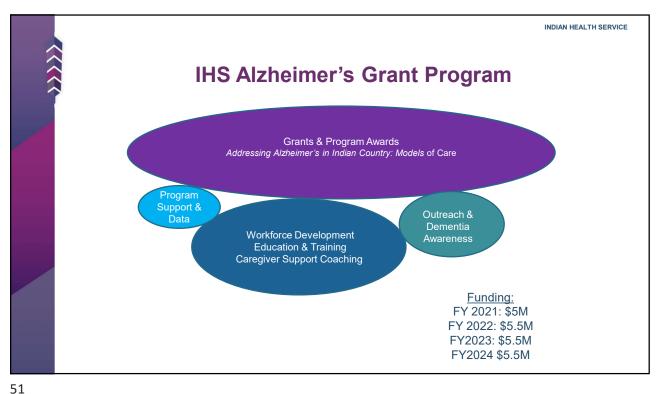
Prescribing Information

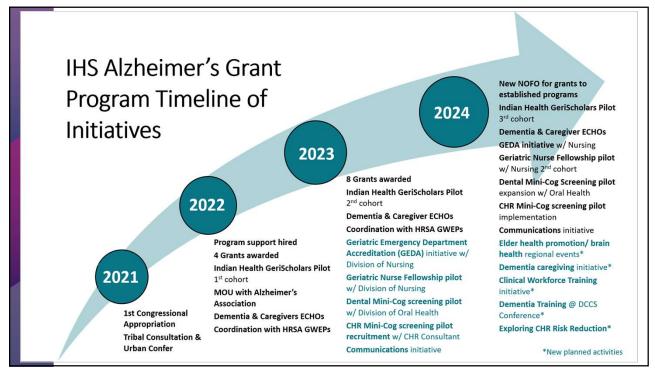
- Boxed warning for the risk of ARIA and potential for serious outcomes
 - Because ARIA-E can cause focal neurologic deficits that can mimic an ischemic stroke, treating clinicians should consider whether such symptoms could be due to ARIA-E before giving thrombolytic therapy in a patient being treated with KISUNLA
 - Increased risk of ARIA in ApoE ε4 homozygotes; recommend ApoE ε4 genotype testing to inform risk
 - Contraindication for patients with serious hypersensitivity to donanemab

www.fda.gov 48









INDIAN HEALTH SERVICE

INDIAN HEALTH SERVICE

Grants and Program Awards Addressing Dementia in Indian Country: Models of Care

"...to support the development of models of comprehensive and sustainable dementia care and services in Tribal and Urban Indian communities that are responsive to the needs of persons living with dementia and their caregivers."

2024 - Addressing Dementia in Tribal and Urban Indian Communities: Enhancing Sustainable Models of Care - applications in review

- 3 years funding support for programs with established efforts to address dementia
- Further development of current models of care and sustainability

2023 - 8 Awards

- Absentee Shawnee Tribal Health System (OK)
- Cherokee Nation Health Systems (OK)
- The Cheyenne and Arapaho Tribes (OK)
- The Confederated Tribes of Grand Ronde Community of Oregon (OR)
- The Fallon Paiute-Shoshone Tribe (NV)
- The Kenaitze Tribe (AK)
- The Norton Sound Health Center (AK)
- The Seattle Indian Health Board (WA)

2022 - 4 Awardees - entering into their 2nd year

- The Indian Health Board of Minneapolis, Inc. (MN)
- The Indian Health Council, Inc. (CA)
- The Nez Perce Tribal Health Authority (ID)
- The Northern Valley Indian Health (CA)

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Workforce Development and Capacity Building

Indian Health Geriatric Scholars

· 24 applicants for 2024 cohort

Geriatric Nurse Fellowship in partnership with IHS Division of Nursing 16 APRNs, RNs, and LPNs from 9 states and 7 IHS regions completed first year pilot

- - Addressing: medication safety, education, and compliance; palliative care and advanced directives, cognitive screenings, falls prevention, STIs, aging well
- **Indian Country Dementia Clinical and Caregiver ECHOs**
 - Hosted monthly by the Northwest Portland Area Indian Health Board

Dental Clinic Early Dementia Detection Initiative Continues

With IHS Division of Oral Health

Community Health Representatives (CHR) Dementia Detection Initiative

- With IHS CHR program
- Partnering with Oklahoma University Dementia Care Network (GWEP) for dementia training

Geriatric Emergency Department Accreditation (GEDA) Initiative Continues

With IHS Division of Nursing

INDIAN HEALTH SERVICE

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Outreach and Awareness

- Regional elder-focused health and wellness events in partnership with the Health Promotion and Disease Prevention program – Brain Health focus
- Communications support contract
 - e-news, video and photo assets, website development
- National Caregiver Month blog and social media campaign
- Alzheimer's and older adult observances via social media
- · Tribal leader updates highlighting work across IHS, Tribal, and Urban Indian communities
- YouTube channel for training and webinars
- · Online calendar of events
- · Listserv and community continue to grow!

Program Support and Data

- · Enhanced Technical Assistance to IHS Grantees
- · Data Dashboard in development
- First Annual Report to Congress in review

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INDIAN HEALTH SERVICE

For More Info

The IHS Alzheimer's Grant Program

www.ihs.gov/alzheimers/

2024 Alzheimer's Grant Program funding opportunities

 https://www.ihs.gov/alzheimers/fundingopps/2024fu ndingopp/

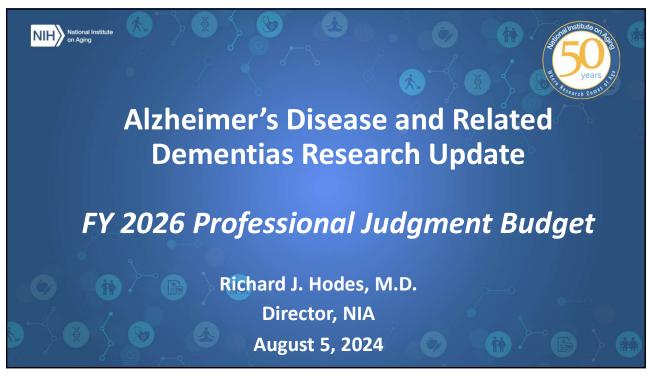
Education and training resources and opportunities

www.ihs.gov/alzheimers/alztraining/

Dementia information and links

 www.ihs.gov/alzheimers/informationresources/alzde mentiaresources/

Stay Connected and join the <u>IHS Elder Care Listserv</u> at www.ihs.gov/alzheimers/





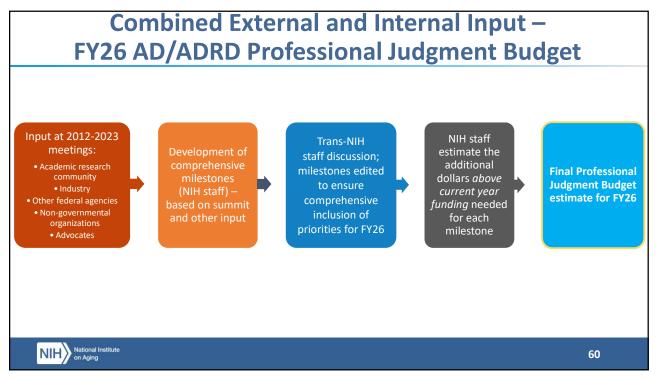
Professional Judgment Budget Language

SEC. 230. Hereafter, for each fiscal year through fiscal year 2025, the Director of the National Institutes of Health shall prepare and submit directly to the President for review and transmittal to Congress, after reasonable opportunity for comment, but without change, by the Secretary of Health and Human Services and the Advisory Council on Alzheimer's Research, Care, and Services, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institutes) for the initiatives of the National Institutes of Health pursuant to the National Alzheimer's Plan, as required under section 2(d)(2) of Public Law 111–375.



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Using CADRO as a Framework

- The eight CADRO (Common Alzheimer's Disease Research Ontology) categories provide the overarching framework for the FY 2026 Professional Judgment Budget and narrative.
- CADRO provides the framework for IADRP (the International Alzheimer's Disease Research Portfolio) and allows tracking of implementation across research areas.



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AD/ADRD Professional Judgment Budget FY 2026, Projected Costs and Additional Resources Needed

Professional Judgment Budget FY26 Additional Resources Needed	Amount
Epidemiology/Population Studies	\$60,000,000
Disease Mechanisms	\$20,000,000
Diagnosis, Assessment, and Disease Monitoring	\$82,000,000
Translational Research and Clinical Interventions	\$148,000,000
Dementia Care and Impact of Disease	\$26,475,000
Research Resources	\$59,000,000
Alzheimer's Disease-Related Dementias	\$40,000,000
Staffing Needs and Administrative Support	\$10,010,000
Total Costs for new AD/ADRD Research	\$445,485,000
Less: Funding from completed projects that is now available for new AD/ADRD research	(\$332,000,000)
Additional FY26 Resources Needed for New AD/ADRD Research	\$113,485,000

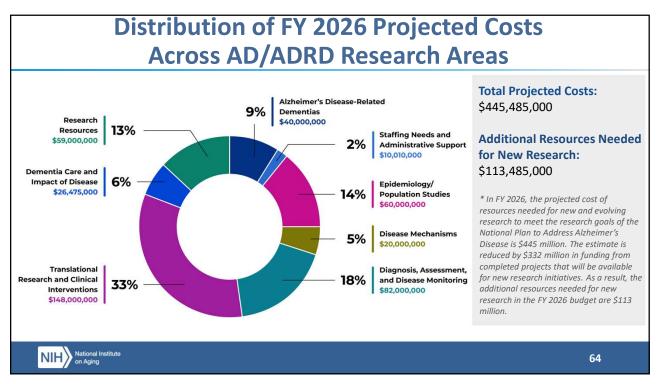


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Total Resource Needs, FY 2026 AD/ADRD Research	
Professional Judgment Budget FY26 Total Resources Needed	Amount

Professional Judgment Budget FY26 Total Resources Needed	Amount
FY24 NIH Estimate (based on FY24 enacted dollars) for AD/ADRD Research Spending (baseline estimate)	\$3,871,000,000
Additional FY26 Resources Needed for New AD/ADRD Research	\$113,485,000
Total FY26 Resources Needed for AD/ADRD Research	\$3,984,485,000





FY 2026 Professional Judgment Budget Narrative: Examples of Potential Future Research Opportunities

- Organized by six research areas, with an additional cross-cutting area.
 - > Epidemiology/Population Studies
 - > Disease Mechanisms
 - > Diagnosis, Assessment, and Disease Monitoring
 - > Translational Research and Clinical Interventions
 - > Dementia Care and Impact of Disease
 - > Research Resources
 - > Cross-cutting Area: Community Engaged Research





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FY 2026 Professional Judgment Budget Narrative: Examples of Potential Future Research Opportunities

- Epidemiology/Population Studies
 - > Expand research on genomic analyses of Alzheimer's and related dementias to better understand dementia risk and resilience.
- Disease Mechanisms
 - > Explore the role of the gut microbiome in dementia risk and resilience.
 - > Expand research exploring the roles of brain immunity in dementia development.
 - > Enhance understanding of the roles of abnormal proteins in dementia.
 - > Examine the mechanisms underlying cognitive fluctuations associated with dementia.



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FY 2026 Professional Judgment Budget Narrative: Examples of Potential Future Research Opportunities

Diagnosis, Assessment, and Disease Monitoring

- > Expand research efforts to identify new disease-associated proteins.
- > Develop new approaches to support decision-making for early dementia diagnosis and risk disclosure.

Translational Research and Clinical Interventions

- > Accelerate the transition of drug candidates from phase 1 to phase 2 trials.
- > Expand the use of newly available biomarkers in trials.
- > Enhance efforts to recruit and retain clinical trial participants, including those from diverse populations.
- > Integrate multiple data types across the research pipeline to support the development and application of a precision approach to prevent and treat AD/ADRD.



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FY 2026 Professional Judgment Budget Narrative: Examples of Potential Future Research Opportunities

Dementia Care and Impact of Disease

> Expand research on development and exploration of innovative care interventions and dementia care models.

Research Resources

> Expand efforts to enhance data in existing data resources to enable researchers to tackle new, more complex research questions.

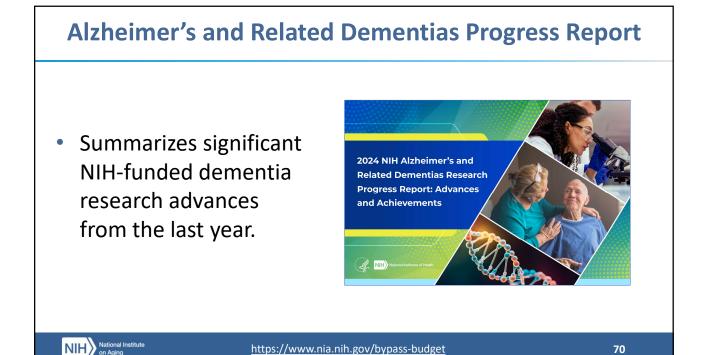
Cross-cutting Area: International Studies

> Build capacity for community-engaged Alzheimer's and related dementias research, including research to understand and address the drivers of dementia health disparities in diagnosis, treatment, and outcomes.



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Alzheimer's and Related Dementias Progress Report

Features a summary of the achievements of the past year, including:

- o Advancing our understanding of the risk and protective factors, genetics, and mechanisms of dementia
- o Expanding large and complex data sets in accessible platforms to speed up translational research on therapeutic candidates
- o Diversifying and de-risking the therapeutic pipeline for disease-modifying drugs
- o Accelerating drug repurposing and combination therapy development
- o Developing tools to detect, diagnose, and monitor dementia
- o Advancing clinical research on lifestyle interventions
- o Increasing our understanding of how social and environmental factors affect dementia risk and disparities
- o Expanding research on dementia care and care partner interventions
- o Enhancing diversity and inclusion in clinical trials



https://www.nia.nih.gov/bypass-budget

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Implementation Tracking

- NIH AD/ADRD Milestone Database for tracking funding initiatives and activities: https://www.nia.nih.gov/research/milestones
 - Searchable content
 - o Aimed at addressing the research milestones associated with NAPA
 - o Includes information on milestone activities, status, etc.
- IADRP: http://iadrp.nia.nih.gov/
 - Will continue to offer detailed tracking of awards under the CADRO categories
 - o Currently being updated to improve features for the research community



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Save the Date: 2024 NIH Alzheimer's Research Summit NIH National Institute on Aging 2024 NIH Alzheimer's **Research Summit Building a Precision Medicine Research Enterprise** September 23rd — 25th

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NIH National Institute on Aging

NIA's 50th Anniversary

https://www.nia.nih.gov/2024-alzheimers-summit

Registration is now open!

- 2024 marks the **50**th **anniversary** of the National Institute on Aging
- Since 1974, NIA has led broad scientific efforts to understand the nature of aging and to extend the healthy, active years of life
- Learn about **major milestones** in NIA's history: www.nia.nih.gov/50years



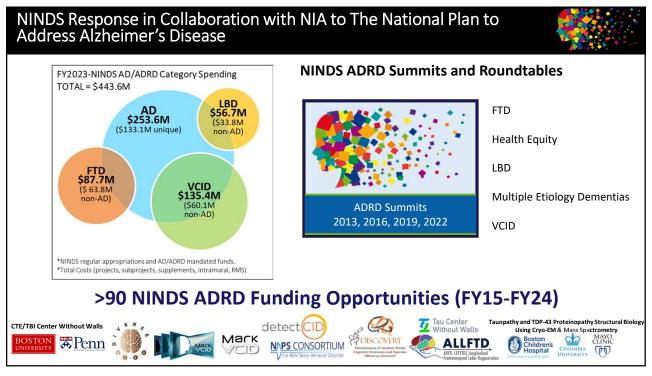
To celebrate, NIA is conducting a series of activities throughout 2024 to highlight progress over the past 50 years and to inspire future generations of aging researchers.



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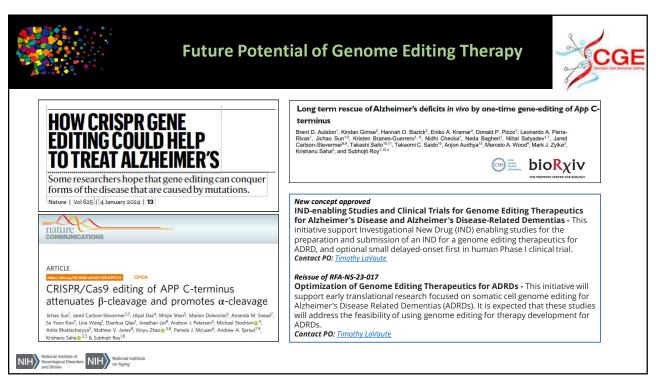


DetectCID: 5-Cog Paradigm Clinical Trial Results (6/2024) Improved Primary Care Diagnosis & Management In Patients With Cognitive Concerns Non-Literacy Biased, Culturally Fair Cognitive Detection Tool in Primary Care Patients with Cognitive Concerns: Memory recall, gait, symbol matching to pictures with EMR integration ☐ Dementia is often undiagnosed in primary care, and even Control (N=600) 5-Cog (N=592) when diagnosed, untreated ☐ Missed detection delays provision of support services and critical planning 10% ☐ Underdiagnosis is even more prevalent among older Black and Hispanic patients than among White patients 5% ☐ Randomized trial in urban primary care with 1,200 primarily Black & Hispanic older adults with cognitive concerns ☐ A key is EMR integration of results with suggested follow-up MCI or New Improved Specialist **Imaging** ordered The 5-Cog paradigm helped improve dementia care actions related to diagnosis, investigations, and treatments that accounts for many implementation barriers and racial/ethnic differences in primary care patients presenting with cognitive concerns.

Joe Verghese et al., Nature Medicine, (2024) https://doi.org/10.1038/s41591-024-03012-8 (Supported by NIH grants UG3NS105565, U01NS105565)

Rachel Chalmer et al. Neurodegener. Dis. Manag. 12(4): 171–184. (2022) (Supported by NIH grants UG3NS105565, UH3NS105565)

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NINDS Alzheimer's Disease-Related Dementias (ADRD) Program NINDS has 21 open/planned ADRD funding initiatives. For more information see NINDS Focus on Alzheimer's Disease and Related Dementias page: https://www.ninds.nih.gov/Current-Research/Focus-Disorders/Alzheimers-Related-Dementias No RFA is needed to apply!! NINDS special AD/ADRD payline applies to investigator-Initiated research applications to the NIH Parent R01 and the NINDS R21 (PA-21-219) Published funding announcements will also be shared via the NINDS ADRD Listserv Email kiara.bates@nih.gov to sign up! **Training & Career Research Resource** Disease Mechanisms **Translation Clinical Trials, Clinical Research AD/ADRD Research Supplements to Promote Diversity** in Health-Related Research NOT-NS-24-071, PA-23-189

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