

LEADING THE CHARGE

Expanding Collaborative, Cross-Disciplinary Research for the Prevention, Treatment, and Care of Dementia



NIH Professional Judgment Budget for Alzheimer's Disease and Related Dementias for Fiscal Year 2022

The National Institutes of Health (NIH) presents an annual Professional Judgment Budget for additional federal funds needed to treat or prevent Alzheimer's disease and related dementias by 2025. This report outlines the toll these diseases take on our nation and the scientific opportunities we could pursue with enhanced funding in fiscal year (FY) 2022. To view the entire NIH Professional Judgment Budget for FY 2022, visit www.nia.nih.gov/bypass-budget.

Dementia Affects Millions of Americans

Experts have estimated that as many as 5.8 million Americans aged 65 and older in 2020 have **Alzheimer's disease** dementia, and its prevalence in the United States is projected to increase to 13.8 million people by 2050. Although Alzheimer's is the most common dementia diagnosis, many people have other forms of dementia such as **Lewy body disease**, **frontotemporal disorder**, and **vascular cognitive impairment**, either alone or, more commonly, mixed with Alzheimer's changes.

Dementia Is a Leading Cause of Death among Americans

Alzheimer's is the sixth leading cause of death for Americans. In 2017, it accounted for an estimated 120,000 deaths.

Investing Now for Effective Preventions, Treatments

NIH estimates needing **\$3.107 billion** for research on Alzheimer's and related dementias in FY 2022. This bypass budget proposal compensates for the reduction proposed in the FY 2021 President's budget for Alzheimer's and related dementias, considers funds expected to become available from completed initiatives, and concludes that **\$289 million** in additional resources is needed to reach the 2025 goal.

Dementia Is Costly

Dementia has an enormous impact on family caregivers, long-term care facilities, health care providers, health care systems and infrastructure, and the communities in which we all live. An analysis conducted by NIH-supported researchers found that total social costs from health care and caregiving spending for a person with probable dementia in the last five years of life was an estimated \$287,000, compared with \$175,000 for an individual with heart disease and \$173,000 for someone with cancer.

As NIH was in the process of analyzing progress and formulating the FY 2022 budget recommendation, the COVID-19 pandemic began and rapidly evolved. As a result, NIH and the broader research community began to consider new areas of research with relevance to Alzheimer's and related dementias, such as studies on the susceptibility of people living with these conditions to COVID-19. In particular, people living with dementia in nursing homes and long-term care facilities are especially vulnerable, but little is known about how to reduce their risk of infection or improve their care or how COVID-19 infection may interact with structural and functional changes that occur in Alzheimer's disease. Research in these areas has now begun.

The immediate and future impact of COVID-19 on the conduct of Alzheimer's and related dementias research, as for all biomedical research, is uncertain. With continued public support of these research initiatives, NIH is poised to continue making great strides in progress despite any setbacks due to COVID-19. Thanks to previous investments, we have the infrastructure in place to achieve our research milestones for the prevention, treatment, and care of dementia through comprehensive, collaborative research.

Recent Advances, New Initiatives in Alzheimer's and Related Dementias Research

Through the recent substantial investments in research, NIH continues to advance scientific growth and discovery to improve the diagnosis, treatment, and care of those living with dementia. NIH-supported scientists are identifying and testing new drug candidates, advancing comprehensive models of care, developing new biomarker tests, exploring disease risk and protective factors, and improving the understanding of the role of genetics and other disease mechanisms.

Testing new drug candidates and behavioral interventions

To accelerate discovery of effective treatments, NIH has developed programs to make data, knowledge, and research tools widely available to all researchers. Industry, academia, and government are now collaborating in unprecedented ways to reach a common goal: developing effective treatments for Alzheimer's and related dementias.

NIH has increased drug discovery significantly, thanks in large part to the considerable investment in Alzheimer's and related dementias research over the past several years. Of the many compounds in NIH-supported drug development programs for Alzheimer's and related dementias, 10 drug candidates have now matured through the pipeline, from discovery in the lab all the way through preclinical development, to reach the stage of human testing. NIA currently supports more than 40 trials testing drug candidates that target many different aspects of the disease, and more than 100 trials testing behavioral and lifestyle interventions.

Increasing the diversity of research participants

With the steady growth in the number of human studies comes the urgent need to recruit far more participants who represent the diversity of the U.S. population. NIH invests in a range of methods, resources, and research to optimize recruitment efforts.

NIH recently funded eight projects at research institutions nationwide to help inform scientists about how to overcome barriers to enrolling and retaining research participants from underserved communities. These

Explore the [NIA-Funded Active Alzheimer's and Related Dementias Clinical Trials and Studies](#) site, which is continuously updated. NIH supports more than 230 studies on a wide range of prevention, treatment, care, and caregiving interventions for people with Alzheimer's and related dementias.

projects include approaches to build trust in communities and engage specific ethnic and racial groups in Alzheimer's and related dementias research.

Advancing comprehensive models of care

To develop behavioral interventions for dementia care providers, NIA recently expanded the network of [Edward R. Roybal Centers for Translational Research in the Behavioral and Social Sciences of Aging](#). The purpose of the network is to translate findings from basic behavioral and social research into evidence-based interventions and programs that can be shared and implemented in the community.

Another recently funded program is NIA's [Imbedded Pragmatic Alzheimer's Disease and Related Dementias Clinical Trials Collaboratory](#), which is designed to bolster the nation's capacity to conduct pragmatic clinical trials to improve dementia care within health care systems. Through this effort, researchers will test care interventions in real-world settings such as hospitals, assisted living facilities, nursing homes, and adult day centers.

Developing novel biomarkers

NIH funding has enabled significant recent progress in developing, testing, and validating biomarkers for diagnosing Alzheimer's and related dementias. These technological advances have helped scientists discover that changes in the brain that occur during Alzheimer's are evident long before a person shows outward signs of cognitive impairment or dementia.



Within the past year, several different teams of NIH-supported scientists have reported advances in the development of blood-based tests that could enable rapid screening of research volunteers. Using a blood test to screen could reduce the number of research volunteers who undergo invasive spinal taps and expensive brain imaging with PET (positron emission tomography) scans.

For now, these blood tests can be used only by researchers in clinical studies. It is likely that eventually, FDA-approved tests will be made available to physicians, enabling them to screen their patients for Alzheimer's and related dementias before symptoms appear.

Exploring risk factors and health disparities

By studying large, diverse groups of people, researchers can identify which genes, behaviors, and lifestyle choices are linked with the development of dementia. New studies have analyzed the impact that treating high blood pressure and maintaining heart health, staying socially connected and engaged, and adopting healthy lifestyle habits may have on the risk of developing dementia.

Developing a better understanding of how and why Alzheimer's and related dementias affect diverse communities in different ways is paramount to the search for treatments and prevention. NIH-supported studies of health disparities have already identified many factors, including race, ethnicity, sex, level of education, geography, and socioeconomic status, that may influence the development of these diseases. NIH is committed to supporting studies on risk factors related to health disparities and is currently funding more than 60 related research projects at universities across the country. NIH also invests in optimizing recruitment efforts because engaging diverse research participants is crucial to assessing and addressing health disparities.

Understanding disease mechanisms

NIH's research investments to identify the biological mechanisms that lead to Alzheimer's and related dementias are fundamental for the discovery of potential drugs that target them. There are many biological pathways that scientists can target with investigational drugs. For example, several recent studies have further illuminated how components of the immune system, brain inflammation, and possibly viruses and bacteria contribute to the development of Alzheimer's and related dementias.

Scientists also search for mutations in genes because these variations might contribute to or prevent development of disease. In 2019, a team of geneticists reported that a variant of a certain gene may play a role in providing protection against Alzheimer's. This discovery may provide a new direction toward developing an effective treatment.

Building an infrastructure for translational research

NIH has launched several programs over the past six years to provide researchers with novel collaboration opportunities and improved infrastructure for translating their ideas for drugs and other products from the laboratory to public health benefit. A prime example is NIA's signature **Accelerating Medicines Partnership - Alzheimer's Disease (AMP-AD)** program. More than 3,000 academic and industry researchers have shared and accessed AMP-AD data and other resources, identifying more than 500 unique candidate drug targets so far.

Read more about recent research advances and new initiatives at www.nia.nih.gov/bypass-budget.



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