CBSD Center for Biomedical System Design / NEWDIGS

TuftsMedicine Tufts Medical Center

Executive Brief
Advancing System Readiness for Alzheimer's Disease Breakthroughs

Over the next 25 years, more than 13 million adults in the United States, and 140 million worldwide, will be diagnosed with Alzheimer's disease and other forms of dementia. This wave of disease will profoundly impact families, the health care system, and the broader economy.

In the U.S. alone, the current cost of treating those with Alzheimer's disease is estimated at $384 billion, including costs to Medicare and Medicaid as well as out of pocket spending by patients and their families. Spending to care for those with Alzheimer's could reach $1 trillion by 2050, according to the Alzheimer's Association.

The Food and Drug Administration has approved two disease-modifying therapies (DMTs), Leqembi® (lecanemab-irmb) and Kisunla® (donanemab-azbt), that slow Alzheimer's disease progression and a robust Alzheimer's drug development pipeline promises more therapies in coming years. In addition, diagnostic innovations, including blood tests that can detect biomarkers of the disease at its earliest stages and digital cognitive assessment tools, make early diagnosis much more accessible and can accelerate the patient's path to treatments that slow disease progression.

Despite these scientific advances, persistent challenges in the way the health care system is organized affect every aspect of care for patients with Alzheimer's disease. These constraints hinder the system's ability to diagnose Alzheimer's disease in early, treatable stages where new, groundbreaking treatments can help slow the progression of this devastating and costly disease.

There is widespread underdiagnosis of the early stages of Alzheimer's disease

More than 92% of adults with early-stage Alzheimer's and experiencing mild cognitive impairment lack a formal diagnosis. Early detection and diagnosis are critical, since DMTs are not approved for treatment of later stages of Alzheimer's disease. DMTs have been shown to slow the progression of Alzhei-

Background

This Executive Briefing is the first in a series of reports from the NEWDIGS consortium on strategy to expand patient access to the new generation of disease modifying therapies (DMTs) for early Alzheimer's disease.

The NEWDIGS project on Alzheimer's disease is organized around a hypothesis that ensuring safe, effective, and equitable patient access to DMTs for Alzheimer's disease will require a shift toward a more primary care-centered model of care including detection, diagnosis, treatment, and monitoring.

This brief is a synthesis of multi-stakeholder discussions from an Executive Roundtable in November 2024, working group meetings, and a Design Lab held in Boston (MA) in April 2025. It summarizes major barriers to the delivery of early Alzheimer's care and potential solutions required to overcome these impediments. Work to design and test specific solutions, as well as the encouragement of broad uptake of pilot activities across the U.S. is ongoing and will be covered in future reports in this series.

mer's disease, allowing patients to live independently longer, have a better quality of life, and reduce healthcare and caregiving costs. One economic study found that a one-year delay in progression from mild cognitive impairment to moderate Alzheimer's disease could reduce costs in the U.S. by up to $1.3 trillion over the next 10 years.

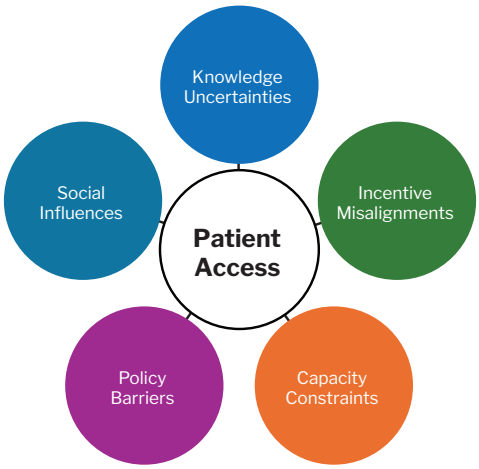
The path to disease modifying therapy is complex, expensive, and time consuming

Currently, the initiation of DMTs for early Alzheimer's disease is the end result of a complex, multi-step process. This lengthy process is at odds with the reality of the disease: Alzheimer's disease is progressive and neurodegenerative. Minimizing time-to-therapy is crucial or else the patient may progress to a more severe stage of the disease and no longer be eligible for DMTs.

Diagnosis, determination of treatment eligibility and administration of therapy defaults to specialists

Though primary care providers make up to 80% of initial diagnoses of dementia, primary care teams have limited training and capabilities to expedite diagnosis, resulting in most of the diagnostic process being referred to neurologists, with reliance on brain imaging (PET and MRI) to confirm AD pathology. This adds costs and creates critical delays for patients. One 2019 study found that only 36% of patients with preliminary diagnoses of dementia were seen by a specialist within 5 years, with average wait times of 18 months to see a specialist. Delays to see specialists often mean that the disease has progressed beyond the stage where disease modifying therapies are effective and clinically indicated.

Barriers to health system readiness for advances in science



We divide barriers and solutions into five main dimensions, with examples:

- **Knowledge Uncertainties:** Evidence gaps; patient & clinician education
- **Incentive Misalignment:** Benefit designs and payment models; non-financial risks and rewards
- **Capacity Constraints:** Infrastructure and workforce gaps; administrative bottlenecks; outcomes tracking
- **Policy Barriers:** Regulation; standards of care; privacy protections
- **Social Influences:** Geography; socioeconomic factors; stigma and bias

A paradigm shift to primary care is needed

The current diagnostic and treatment paradigm relies too heavily on access to medical specialists such as neurologists. Neurologists and other dementia-specialists are in short supply and are unevenly distributed throughout the U.S. At least 20 states are considered "neurology deserts," with enormous gaps between the number of practitioners available and the growing population of patients needing care. Limited access to specialists often results in protracted delays in diagnosis, and increased costs for patients and payers.

Diagnosis and treatment for the growing population of Alzheimer's patients must shift to the primary care setting. Primary care providers need access and training in the use of early diagnostic tools and life-changing treatments to allow patients to be cared for in an appropriate, timely, and equitable way. Primary care physicians and other frontline primary care professionals are closest to patients and their families, and trusted partners in care—a critical component in reducing the fear and stigma some patients may experience.

Shifting early detection, diagnosis, and treatment of early Alzheimer's disease into primary care represents a significant expansion of the usual care practiced by primary care physicians and their teams. Primary care physicians are already overburdened and the number of physicians entering primary care has declined leading to workforce shortages.

Systemic change is needed to enable this necessary change. The magnitude and complexity of the challenge of primary care workforce capacity cannot be solved in a scalable, sustainable way with a single solution or intervention to create access to care on a scale commensurate with the prevalence of early Alzheimer's disease.

However, there are existing, widely accepted models that can serve as a foundation. For example, primary care provider capacity could be extended by implementing a team approach in which other clinical support personnel are enabled to make optimal use of their skills and training.

Alzheimer's disease is a growing public health problem that, left unchecked, leads to loss of quality of life for patients and caregivers, greater institutionalization, and an increased economic burden. Fortunately, scientific advances that can bend the trajectory of the disease are now available. But making these breakthroughs widely accessible is a challenge that requires removing many systemic barriers and developing instead a new framework for care. Additionally, an increasing body of evidence shows that multiple risk factors for dementia are preventable or reversible over a lifetime. Many of these factors, including hypertension and hyperlipidemia, may have a direct impact on triggering diseases of the brain, including Alzheimer's. In fact, leaders in the U.S. neurology community now see "brain health" as an essential target for lifelong care and have called for development of "primary care for the brain."

In the next phase of the NEWDIGS project on Alzheimer's disease, the consortium will design solutions to address:

- Primary care provider shortages and other current limitations in primary care practice
- Early intervention models for frontline providers
- Enabling technology for use in the primary care setting
- Best practices for outcomes tracking

About the Center for Biomedical System Design

The NEWDIGS consortium is dedicated to improving health by accelerating appropriate, timely, and equitable patient access to biomedical products in ways that work for all stakeholders.

Based at the Center for Biomedical System Design at Tufts Medical Center in Boston, NEWDIGS aims to help the health care system catch up with the science of biomedical innovation by removing barriers and designing methods to ensure that cutting-edge treatment is made available to patients. The consortium's collaborators include patients, clinicians, payers, biopharmaceutical companies, regulators, and investors, among others.

Launched at MIT in 2009, the organization moved to Tufts Medical Center in 2022 to be closer to patient care and to longstanding collaborators. Among its successes are payment innovations for durable cell and gene therapies, and regulatory innovations that inspired a European-wide pilot led by the European Medicines Agency focused on Adaptive (Licensing) Pathways.

Its current work focuses on large population health diseases including obesity and Alzheimer's.