

Results of GERAS-US Study Demonstrate Societal Cost Burden for Patients and Caregivers During Early Stages of Alzheimer's Disease

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Early Alzheimer's disease poses financial burdens on patients, caregivers and society

INDIANAPOLIS, May 19, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced baseline results from the GERAS-US Study examining the societal costs associated with mild cognitive impairment (MCI), mild dementia (MILD), and caring for someone with Alzheimer's disease (AD). The study, published today in The-Journal of Alzheimer's Disease, is the first of its kind to show how early stages of cognitive decline economically impact both patients and caregivers. Alzheimer's is a relentless, fatal disease creating a health crisis for patients, families and society. Out of the top six diseases affecting Americans, AD is the only one with no treatment to prevent, cure or slow the disease.

"It is well known that caregiver costs increase with disease severity and this study demonstrates that those costs are incurred even earlier than we expected, at the stage of mild cognitive impairment. Clearly, memory loss in a loved one is not a benign event," says Dorene M. Rentz, co-author, PsyD, Professor of Neurology at Harvard Medical School. "It has a detrimental impact on caregivers and families long before a diagnosis of AD dementia. This paper validates the importance of a timely diagnosis and reinforces the emerging science that treatment, even at the preclinical stage of disease, may benefit not only patients, but their caregivers as well."

The cross-sectional assessment used baseline data from GERAS-US, which is a 36 month, US-based prospective, longitudinal cohort study of 1,327 patients diagnosed with early AD seeking routine care for memory loss. Patients with MILD AD had significantly higher total societal costs per month than patients with MCI AD, \$4,243 vs. \$2,816. The differences were primarily due to the increased need for caregiver support. Forty-five percent of overall costs were informal caregiver costs in the MILD group, while thirty-nine percent of overall costs were direct medical patient costs in the MCI group. The time spent by caregivers on basic activities such as assisted daily living services (ADLs), instrumental ADLs, such as shopping, cooking, cleaning, laundry, taking medicine, and supervision was twice as high for the MILD vs. MCI group. GERAS-US is the first study to examine costs for patients with MCI or MILD AD based on amyloid positron emission tomography (PET) testing.

"It is important to recognize that Alzheimer's disease represents a neurodegenerative continuum that shows, even in the earliest phase, cognitive deficits often lead to functional decline. This exacerbates the physical, emotional, and economic burden associated with progression into the early stages of dementia," says Ronald L. Schwartz, MD, co-author and GERAS-US site investigator. "By using tools such as amyloid PET imaging, clinicians can improve diagnostic accuracy which allows for more focused management of both dementia as well as relevant co-morbidities which may influence neurocognitive changes associated with aging."

Research indicates the pathophysiology of AD begins decades before symptoms start to manifest. The disease is currently assessed by symptoms and their progression. Findings from this study suggest that AD assessments should evolve to include standard tools or methods to evaluate the underlying pathology and allow for this baseline data to be captured in healthcare systems.

"A timely and accurate diagnosis enables physicians to better manage their patients' medical comorbidities and assists caregivers' planning for present and future care needs," says Howard Fillit, MD, Founding Director and Chief Scientific Officer, Alzheimer's Drug Discovery Foundation, and co-author. "An early diagnosis also allows patients and loved ones to make choices about enrolling in a clinical trial as part of their plans."

For over 30 years, Lilly has been committed to bringing innovative Alzheimer's disease therapies and diagnostics to patients and continues to lead the field in research, which also includes identifying biomarkers to support early detection of the disease.

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About The Journal Of Alzheimer's Disease (JAD)

Now in its 22nd year of publication, the Journal of Alzheimer's Disease is an international multidisciplinary journal to facilitate progress in understanding the etiology, pathogenesis, epidemiology, genetics, behavior, treatment, and psychology of Alzheimer's disease. The journal publishes research reports, reviews, short communications, book reviews, and letters-to-the-editor. Groundbreaking research that has appeared in the journal includes novel therapeutic targets, mechanisms of disease, and clinical trial outcomes. The Journal of Alzheimer's Disease has a 2018 Journal Impact Factor of 3.517 according to Journal Citation Reports (Web of Science Group, 2019). JAD is published by IOS Press. www.j-alz.com

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about amyloid PET imaging and reflects Lilly's current beliefs. Among other things, there is no guarantee that future study results will be consistent with study findings to date. For further discussion of these and other risks and uncertainties, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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¹ Jack CR, Knopman DS, Jagust WJ, et al. Tracking pathophysiological processes in Alzheimer's disease: an updated hypothetical model of dynamic biomarkers. Lancet Neurol. 2013;12(2):207-216. http://dx.doi.org/10.1016/S1474-4422(12)70291-0.



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