

## FREQUENTLY ASKED QUESTIONS

### **Publication of New Criteria and Guidelines for Alzheimer's Disease Diagnosis April 2011**

For the first time in 27 years, new criteria and guidelines for the diagnosis of Alzheimer's disease have been published. The initial diagnostic criteria for the disease were published by the Alzheimer's Association and the National Institute of Neurological and Communicative Disorders and Stroke in 1984. The new criteria and guidelines are the result of work that began two years ago, when three expert workgroups consisting of a total of more than 40 Alzheimer's researchers and clinicians from around the globe began the in-depth process of reviewing the original criteria and deciding how they might be improved by incorporating research advances from the last three decades. Formation of the workgroups was spearheaded by the Alzheimer's Association and the National Institute on Aging (NIA) of the National Institutes of Health.

#### **How are they different from the original criteria?**

Two notable differences are that they (1) identify three stages of the disease, with the first beginning before symptoms such as memory loss occur and before one's ability to carry out everyday activities are affected; the original criteria require memory loss and a decline in thinking abilities severe enough to affect daily life (2) incorporate biomarker tests (tests that measure biological changes in the brain associated with Alzheimer's). The original criteria were based chiefly on a doctor's clinical judgment about the cause of a patient's symptoms, taking into account reports from the patient, family members and friends, results of cognitive testing, and general neurological assessment. The new criteria and guidelines propose the addition of biomarker tests, which provide information about biological processes underlying symptoms.

#### **What are the stages of Alzheimer's disease identified by the new criteria and guidelines?**

The three stages are (1) preclinical Alzheimer's disease, (2) mild cognitive impairment (MCI) due to Alzheimer's disease (MCI), and (3) dementia due to Alzheimer's disease.

Preclinical Alzheimer's Disease — Measurable changes in biomarkers that indicate the earliest signs of disease, before symptoms such as memory loss and confusion about time or place are noticeable. This reflects current thinking that Alzheimer's begins creating measurable changes in the brain years, perhaps decades, before symptoms occur. While the criteria and guidelines identify this as a stage of Alzheimer's disease, they do not establish diagnostic criteria that doctors can use now. Rather, they propose additional biomarker research to tell doctors what biomarker results confirm that a person is in this — or another — stage of the disease.

MCI due to Alzheimer's Disease — Mild changes in memory and thinking abilities that are noticeable to the person and to family members and friends and that can be measured, but that do not affect one's ability to carry out everyday activities. Many, but not all, people with MCI go on to develop dementia due to Alzheimer's disease. The guidelines define four levels of certainty for ruling out other causes of MCI and arriving at a diagnosis of MCI due to Alzheimer's disease.

Dementia due to Alzheimer's Disease — Memory, thinking and behavioral symptoms that impair a person's ability to function in daily life.

### **What is a biomarker?**

A biomarker is something in the body that can be measured and that reliably indicates the presence or absence of disease, or the risk of later developing a disease. For example, blood glucose levels are a biomarker of diabetes, and cholesterol levels are a biomarker of heart disease risk. Results of both fluid (e.g., cerebrospinal fluid and blood) and brain imaging (e.g., magnetic resonance imaging and positron emission tomography) tests are being studied as possible biomarkers for Alzheimer's. Two biomarker categories are identified in the criteria and guidelines: (1) biomarkers showing the level of beta-amyloid accumulation in the brain and (2) biomarkers showing that nerve cells in the brain are injured or actually degenerating. The use of biomarkers for all three stages of the disease is proposed, but is intended only for research at this time.

### **What do you hope to accomplish with these new criteria and guidelines?**

An overarching goal of Alzheimer's doctors and researchers, the Alzheimer's Association, and the NIA is to enable people to live long, healthy lives free of the disability caused by Alzheimer's. There is consensus that treating the disease before symptoms occur is how this goal will be met. However, no generally accepted way exists to identify Alzheimer's at its presymptomatic — and potentially most treatable — stage.

### **What do they mean for people already diagnosed with Alzheimer's?**

In the short-term, they will probably not affect how people with Alzheimer's and their family members interact with doctors regarding the disease. There are no new tests that one should be asking for now. Many of the tests that may someday improve diagnostic accuracy or enable pre-symptomatic detection of Alzheimer's disease are available only to people participating in research studies. (Visit [www.alz.org/trialmatch](http://www.alz.org/trialmatch) or call 1-800-272-3900 to learn about research studies in your area.)

### **What do they mean for doctors and researchers?**

Doctors — The new criteria and guidelines are not a call for immediate preclinical diagnosis of Alzheimer's. The recommendations in the article on *preclinical Alzheimer's disease* are intended for research purposes only. They have no clinical utility at this time. The articles create guidelines for *MCI due to Alzheimer's disease* to distinguish it from mild cognitive decline due to other causes. The criteria can be applied in doctors' offices today. They are similar to criteria used in specialist memory centers and research studies. Likewise, for *dementia due to Alzheimer's disease*, they clarify existing guidelines and can be used in doctors' offices today. They are similar to the original criteria, but propose a system of making this diagnosis more certain through the use of biomarkers.

Researchers — The articles offer new guidelines to test experimental approaches for detecting disease and add greater certainty to the diagnosis of Alzheimer's dementia. The additional biomarker research suggested, if successful, will help researchers by identifying individuals at increased risk of developing Alzheimer's — the individuals best suited for studies of new Alzheimer's treatments. Recruiting individuals with increased risk into such studies will decrease the length and cost of studies and speed research discoveries.

**What are the next steps?**

Much additional research needs to be done to validate the use of biomarkers as they are proposed in the new criteria and guidelines. These studies are likely to take a decade or more to fully accomplish. As more is learned about Alzheimer's disease, that new knowledge will be incorporated into the diagnostic criteria and guidelines as they continue to evolve.

**The Sponsoring Organizations**

Alzheimer's Association — The Alzheimer's Association is the world's leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer's disease through the advancement of research; to provide and enhance care and support for all affected; and to reduce the risk of dementia through the promotion of brain health. For more information, please visit [alz.org](http://alz.org), or call 800-272-3900.

National Institute on Aging (NIA) — NIA, part of the National Institutes of Health, a component of the U.S. Department of Health and Human Services, leads the federal government effort conducting and supporting research on aging and the health and well being of older people. For information on age-related cognitive change and neurodegenerative disease, go to the NIA's Alzheimer's Disease Education and Referral (ADEAR) Center at [www.nia.nih.gov/Alzheimers](http://www.nia.nih.gov/Alzheimers).