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New guidelines for early diagnosis of Alzheimer's trigger debate

By Paula Hartman-Stein, Ph.D.

Newly proposed diagnostic guidelines for Alzheimer's disease developed by experts convened by the Alzheimer's Association and the National Institute of Aging (NIA) followed by research reported in *The New York Times* (Aug. 9) that a spinal fluid test is accurate to predict Alzheimer's disease set off a vociferous national debate among medical and psychological practitioners.

In mid-July at an international meeting in Hawaii, experts introduced new diagnostic guidelines that include brain scans to detect Alzheimer's disease before clinical symptoms of memory loss are present.

The new guidelines describe criteria for three stages including the pre-clinical phase, mild cognitive impairment and dementia. Under the new guidelines diagnoses will largely depend upon bio-markers found in brain scans and spinal taps.

In a *Times* article (July 13) Paul Aisen, M.D., a researcher at the University of California, San Diego, and a member of the expert panel, said he foresees a day when people in their 50s routinely have biomarker tests for AD, and if the tests indicate the disease is present, they will take medications to halt it. He said that day is far in the future but it is the direction medicine is headed.

Shortly after the proposed guidelines were made public, geriatric neurologist, Peter Whitehouse, M.D., Ph.D., from Case Western Reserve University in Cleveland questioned whether they represent hope or mostly hype.

"The proposed diagnostic guidelines deserve greater scientific, clinical, economic and ethical scrutiny," he said. "There is little point in using multiple forms of invasive and expensive research tests to assign a frightening and imprecise set of diagnostic labels to millions more people, especially without effective therapies being available. The many unfulfilled promises to develop drugs should serve as a warning that this field's marketing is more advanced than its science."

The Aug. 9 *Times* story said the diagnostic changes could help the pharmaceutical industry that is developing new drugs to attack the disease earlier.

In a study appearing in the *Archives of Neurology* in early August, spinal taps and PET scans are described as sources of an accurate biomarker to predict Alzheimer's through detection of amyloid plaques.

"Biomarkers produce false positives," said Cameron Camp, Ph.D., of Solon, Ohio, a cognitive psychologist and member of the 2010 APA Task Force on the Guidelines for the Evaluation of Dementia and Age-related Cognitive decline.

"The use of biomarkers that enable the existence of beta amyloid to be detected in living brains today find individuals with significant levels of it who do not show evidence of dementia," he said.

According to the *Times* (July 13) experts say the new diagnostic criteria will jump the number of those diagnosed with Alzheimer's from the present 5 million to 10 million or 15 million. John Zeisel, Ph.D, president of Hearthstone Alzheimer Care, said this raises ethical questions. "What can those people do with their lives in the present stigmatized

atmosphere of Alzheimer's? Are the anxiety, depression and stress such a diagnosis would lead to and all the associated financial costs worth the knowledge that there is a probability of a future illness?"

As reported in the *Times,* the Alzheimer's Association and participants from the National Institute on Aging held a conference call to clarify their position following criticism of the recommendation to use biomarkers for diagnostic purposes.

"The groups said biomarkers would be used at this stage only for research, with some patients in studies having tests to see how well such brain changes predict disease," according to reporter Gina Kolata.

The preamble of both the 1998 version as well as the newly proposed APA Dementia Guidelines introduced in mid-July and available for public comment until Oct. 20 with the Public Interest Directorate states, "Even after reliable biomarkers have been discovered, neuropsychological evaluation and cognitive testing will still be necessary to determine the onset of dementia, the functional expression of the disease process, the rate of decline, the functional capacities of the individual and, hopefully, response to therapies."

Camp raised concerns about the side-effect profile for drugs prescribed for dementia. "There are multiple examples of evidenced-based effective interventions for persons with dementia that are non-pharmacologic and which can improve mood, increase engagement and quality of life," said Camp. "If a person with dementia is depressed or presents with behavioral challenges, non-pharmacological treatments are available. Such treatments do not present side effects seen when drugs are administered."

Dharma Singh Khalsa, M.D., founding president and medical director of the Alzheimer's Research and Prevention Foundation in Tucson, Ariz., said in an interview in August, "It's useful to know your risk but drugs clearly aren't the answer. Drug companies and others would like you to believe that there is nothing that can be done via an integrative medical approach to prevent memory loss, but in fact many professionals who work in this field observe that diet, supplements, meditation and various types of exercise can help to slow cognitive decline and maximize a person's mental abilities."

Camp said, "An approach which focuses solely on the use of biomarkers alone to diagnose Alzheimer's disease, especially in the absence of evidence of current dementia, and the sole reliance of pharmacologic interventions for treatment of dementia, represents bad science and bad medical practice at this point in time."

In examining what can be done today for people living with dementia, Zeisel said the answer lies in providing the broadest non-pharmacological supports including cultural and community events such as trips to art museums, sightseeing, volunteer opportunities, theatre, films, poetry clubs and sports events that include social and learning opportunities. "The new diagnostic criteria will extend the half-life from 10 to 15 years to 25 to 30 years, making it imperative to realize Alzheimer's is a disability people live with, not a disease they die from."

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