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## Upfront

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### Major Clinical Trial Suggests Alzheimer's Diagnosis May Be Delayed

Patients with mild cognitive impairment (MCI) who took donepezil, a cholinesterase inhibiting drug, slowed the progression of their dementia to an Alzheimer's diagnosis, according to a study funded by the National Institute on Aging.

The purpose of the Memory Impairment Study was to find if donepezil or vitamin E might delay a clinical diagnosis of Alzheimer's in people with MCI and a genetic risk factor for late-onset Alzheimer's disease.

Subjects who took donepezil were at reduced risk of Alzheimer's diagnosis in the first year of the trial. By the end of the three-year study, however, these subjects received no benefit from the drug. Vitamin E was found to have no effect at any point in the study when compared with placebo.

"While the delay in progressing to Alzheimer's disease had a limited effect in this case, it comes at an early stage of memory loss, a critically important time for patients and families hoping that the disease can be held at bay," says Neil Buckholtz, chief of the Dementias of Aging Branch at the National Institute on Aging.

Of 769 study participants with MCI, 212 developed possible or probable Alzheimer's disease within the three years. For the group taking donepezil, the risk of progression to Alzheimer's diagnosis was cut by 58 percent after one year, and by 36 percent the second year. By the end of the study, no risk reduction was shown for this group.

These findings show the possibility for considering donepezil therapy in certain cases. Reported in the April 14, 2005 online issue of *The New England Journal of Medicine*, these findings are the first to suggest that any agent can delay a clinical diagnosis of Alzheimer's disease in people with MCI.

"These findings give me a great deal of hope," Ronald Petersen, PhD, MD, the study's principal investigator, says. "We have not answered the question of whether donepezil reduces the underlying brain changes in Alzheimer's disease, but now we know that for some people, drug therapy did make a real, clinical difference. I think there will be real opportunities in the future to test other therapies for patients with MCI."

### Could NSAIDs Protect Smokers from Oral Cancer?

To protect themselves against oral cancer, smokers may want to pick up a new daily habit-taking nonsteroidal anti-inflammatory drugs (NSAIDs). Light to moderate tobacco smokers who took NSAIDs over extended periods of time had a 65 percent lower risk of developing oral cancer than smokers who did not, according to a population-based study on patients from the Norwegian Institute of Public Health and the Norwegian Cancer Registry.

"The use of NSAIDs among smokers protected against oral cancer development," lead study investigator Jon Sudbo, MD, PhD, DDS, says. "The results of a significant reduction in oral cancer risk, particularly in light to moderate active smokers,

suggest that NSAID use may provide anti-carcinogenetic effect while the smokers are subjecting themselves to tobacco insult."

Sudbo and his colleagues in Norway and the United States analyzed health data on 908 subjects, half of whom had been diagnosed with oral squamous cell carcinoma. They considered the use of acetaminophen and six NSAIDs: aspirin, ibuprofen, naproxene, indomethacine, piroxicame, and ketoprofene. All six types of NSAIDs were effective at reducing the rate of oral cancer.

The effect of the NSAIDs was best for those smokers who were considered 30 or less "pack-year" consumers of tobacco. A pack-year of smoking is defined as averaging one pack of cigarettes per day per year. A person who smokes one pack a day for 30 years is considered a 30 pack-year consumer.

But those who smoke three packs a day for ten years, or two packs a day for 15 years, are also considered 30 pack-year consumers. The effectiveness of taking NSAIDs diminished for smokers whose consumption was greater than a 30 pack-year level. Acetaminophen, a non-aspirin pain relief medication, was found to be ineffective at reducing the risk of developing oral cancer among smokers.

These results were presented at the 96<sup>th</sup> Annual Meeting of the American Association for Cancer Research, in April 2005.

### **NIDCR Awards Grants for Practice-Based Oral Health Research Initiative**

The National Institute of Dental and Craniofacial Research (NIDCR) has awarded \$75 million in grants to establish regional, practice-based research networks that will investigate everyday issues in the delivery of oral health care.

Over the next seven years, each network will conduct 15 to 20 short-term clinical studies to compare different dental procedures, materials, and prevention strategies under a range of patient and clinical conditions. They will also conduct anonymous chart reviews to generate data on diseases, treatment trends, and the prevalence of less common oral conditions.

The goal of the initiative is to build a better evidence base in oral health care. A lack of high-quality research data to guide treatment decisions has led some dentists and dental hygienists to rely on clinical experience alone in some cases, says Lawrence Tabak, NIDCR director.

"What's unique about these networks is they are practice-based," Tabak says. "Practicing dentists and [dental] hygienists will propose and conduct each clinical study in close collaboration with their network colleagues. Thus, the networks will address practical, real-world issues and generate data that will be of immediate interest to practitioners and their patients."

Two years ago, the NIDCR began developing the General Dental Practice-Based Research Networks (PBRN) initiative to expand the evidence base in dentistry. The grants have been awarded to New York University, which will coordinate the East Coast network; the University of Alabama at Birmingham, which will cover the South; and the University of Washington in Seattle, which will oversee the West Coast network. Each network will be a grassroots effort, with 100 or more practicing community dentists and dental hygienists participating in each region.

"Although the PBRNs are located in just three regions of the country, dental professionals in the Midwest, Southwest, Rocky Mountains, or any other part of the country still can get involved," Bruce Pihlstrom, acting director of NIDCR's Division of Populations and Health Sciences, says. "I would encourage dentists and [dental] hygienists who want to get involved to contact the PBRN nearest to them for more information."

Dental professionals may propose clinical studies once the networks are established. The networks will consider each project proposal and, if it considers a project feasible and worthy, will design a study. "The PBRN protocols generally will be short-term studies that involve relatively straightforward procedures," Pihlstrom says. "For example, protocols might evaluate the outcomes of two comparable root canal procedures, third molar extractions, or even different ways of placing a filling. The key is we don't want to overload busy practitioners with tedious, time-consuming protocols that require multiple in-office calibrations. We want to make this as practice and patient friendly as possible."

## **Extra Pounds Don't Necessarily Lead to Early Death, says CDC**

It's no secret that America has a weight problem. Children, adolescents, and young adults today are more overweight than any previous generation in our nation's history. Sixty-five percent of Americans 20 years and older are overweight or obese, and 16 percent of children and adolescents aged 6 to 19 are overweight, according to the latest National Health and Nutrition Examination Survey (NHANES) data.

Research has linked obesity with diseases like diabetes, cancer, heart disease, stroke, and osteoarthritis, to name a few. According to *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity*, obesity in 2000 cost the United States more than \$117 billion in medical and related costs. So, it may have been surprising to some when the Centers for Disease Control and Prevention (CDC) announced that a recent study found that being overweight was not associated with excess mortality. The study, published in the April 20, 2005 issue of the *Journal of the American Medical Association (JAMA)*, found that 87,000 fewer deaths than expected were associated with being overweight.

To estimate the number of deaths associated with body weight in 2000, researchers examined body-mass index (BMI) and mortality rates of U.S. adults participating in the NHANES. BMI is a measure of one's weight to height; 25 or higher is considered overweight by federal guidelines, and 30 and above is considered obese.

The study revealed that those people who were moderately overweight had no greater risk of death than those of normal weight (BMI 18.5 to less than 25). Being obese carried a greater risk of death, but the risk was smaller than previous studies have indicated and appeared to have decreased over time.

The researchers attribute their lower and declining mortality risk estimates to their study methods and to improvements in medical care, especially for cardiovascular disease, the number one cause of death among the obese. Data were taken from nationally representative surveys in which the heights and weights of participants were actually measured, rather than self-reported. The data analysis also accounted for confounding factors like age, sex, race, and tobacco and alcohol consumption.

According to a separate study published in the same issue of *JAMA*, all cardiovascular disease risk factors except for diabetes have decreased at all BMI levels, and the decline appears to be even greater in higher BMI populations. The study found that, over the past 40 years, the prevalence of elevated cholesterol and blood pressure dropped by almost half in all U.S. adults ages 20 to 74, while smoking dropped by about a third. Reductions in the prevalence of high cholesterol levels were most substantial among obese compared to lean individuals. Cardiovascular disease risk factors for obese people have dropped so much, in fact, that they are now lower than those of normal weight people 20 to 30 years ago.