

## **AACE Statement on Women's Health Initiative Studies Related to Cognition and Dementia published in JAMA, May 28, 2003**

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The American Association of Clinical Endocrinologists (AACE) is concerned that widespread media coverage of new studies published in JAMA may cause unnecessary fear and worry among menopausal women.

The publication of two Women's Health Initiative (WHI) sub-studies related to cognition and dementia in the May 28, 2003, issue of JAMA reports further negative effects of the combination pill of conjugated equine estrogen 0.625mg and medroxy-progesterone acetate 2.5 mg (Prempro). In the past, other studies have not shown a negative effect of estrogen or cognition and dementia. It should be noted that these two studies were restricted to women aged 65 years or older and follow-up was limited to a short period mean of only about 4 years.

AACE recognizes the importance of the WHI and its findings. The WHI is a study of older postmenopausal women who might possibly already have the beginning of disorders such as dementia that are not yet clinically a problem. Only 1 in 6 of the study participants are within 5 years of menopause at entry into WHI. This is an age at which dementia is less likely to occur.

In clinical practice, estrogen (with or without a progestin) is prescribed almost exclusively for women in the early postmenopausal years.

AACE believes that women early in the menopause experiencing symptoms likely to be related to their menopause should not be concerned by these new reports. They bear no relationship to the reason they are being considered for hormone therapy. Every clinical trial that has evaluated the benefits of estrogen (with or without a progestin) in women early in the menopause have demonstrated that all FDA approved estrogen preparations are superior to placebo and to other types of therapies, including "natural" medicines, in controlling the disturbing symptoms of menopause.

Even more importantly, women should appreciate that the WHI used a fixed dose combination of a single preparation of estrogen and progestin. All women know that the response to the menopause varies greatly from one woman to the next. Doctors caring for these women are also fully aware of that and prescribe hormone therapy in preparations, combinations, and doses tailored to the needs of the individual woman for whom she or he is caring.

Nothing in the recent reports from the WHI should interfere with that time honored one-on-one patient-physician relationship at the menopause.

AACE emphasizes that the menopause is one of life's transitions and should not be characterized as a disease, even though it may be associated with troubling symptoms. Endocrinologists are trained to evaluate these symptoms and provide appropriate individualized care to minimize the discomfort associated with menopause. We strongly believe that each woman must discuss her own personal

situation directly with her physician.

We also wish to emphasize that AACE's prior position on the WHI remains unchanged. The existing AACE position statement on the WHI follows below:

## **AACE Position Statement on Women's Health Initiative (WHI)**

**Policy:** AACE believes that menopausal hormone therapy considerations must be individualized taking into consideration the benefits, risks and alternatives. It is essential for a woman contemplating menopausal hormone therapy to discuss these issues with her physician.

**Limitations:** AACE recognizes the limitations of the WHI study with respect to the particular preparation used (CEE/MPA), as well as the study population, which is older, more likely to have cardiovascular disease, and less symptomatic from estrogen deficiency than the typical woman being considered for menopausal hormone therapy.

**Indications:** In the absence of contraindications, menopausal hormone therapy is appropriate for women with moderate to severe vasomotor symptoms associated with estrogen deficiency, quality of life symptoms resulting from estrogen deficiency, and significant symptoms related to vaginal atrophy. Although menopausal hormone therapy is also approved for the prevention of postmenopausal osteoporosis and has demonstrated fracture efficacy in the WHI CEE/MPA study, AACE strongly recommends consideration of alternative pharmacologic therapy options for prevention and treatment of osteoporosis in patients not electing to take menopausal hormone therapy. The use of periodic bone density assessments is recommended to determine if and when pharmacologic intervention is needed (see AACE Osteoporosis Guidelines). AACE supports the position that menopausal hormone therapy is not indicated solely for primary or secondary prevention of cardiovascular disease.

**Use:** The use of menopausal hormone therapy should be at the minimum dose that improves symptoms and used for only so long as symptoms remain significant when assessed intermittently off of therapy. Appropriate counseling regarding the risks and benefits is needed in all patients. The type of menopausal hormone therapy, route of administration and dose should be individualized based on the clinical assessment.