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The Women's Health Initiative: An unforgettable decade

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The 10-year anniversary of the historic Women's Health Initiative (WHI) Hormone Therapy Trial report, which radically changed the practice of women's health, will be commemorated in July 2012. In anticipation of this event, two of the world's leading experts in women's health, menopause, and hormone therapy are releasing an editorial in the journal *Menopause*, providing their perspective on this epic study and the lessons learned over the past 10 years.

JoAnn Manson, MD, MPH, DrPH, from Brigham and Women's Hospital (BWH), and Lubna Pal, MBBS, MRCOG, MSc, from Yale University School of Medicine, note that the WHI's 10-year anniversary is a good time to reflect on the pendulum swings and dramatic evolution in our thinking about estrogen and hormone therapy (HT), which changed the lives of millions of women. The authors state in their editorial, "The WHI is an historic trial that has changed clinical practice and, ultimately, has helped lead us towards a more rational interpretation of the place of hormone therapy in menopause management."

The WHI hormone trials were designed to assess the role of HT in the prevention of heart disease, as well as to evaluate the benefits and risks of HT when used for chronic disease prevention. The trials were done in postmenopausal women ages 50-79 (with a mean age of 63) and tested the types of HT (Premarin and Prempro) that were in common use at the time the study started. The estrogen plus progestin trial was stopped three years early because of an increased risk of breast cancer, heart disease, and concerns that the overall risks exceeded the benefits. The

estrogen-alone trial (in women with hysterectomy) showed fewer risks but was stopped one year early due to an increased risk of stroke. Estrogen-alone did not appear to increase risk of heart disease or breast cancer. In fact, estrogen-alone seemed to lower the risk of heart disease in younger women (in the 50-59 year age group) and seemed to have a favorable benefit-risk profile in that age group. However, the harmful findings in the older women in both HT trials tended to be extrapolated to younger women, resulting in dramatic (>70%) reductions in prescriptions for hormone therapy.

Manson, one of the principal investigators of the WHI since the start of the study and current president of the North American Menopause Society, said, "The WHI deserves credit for stopping the growing clinical practice of prescribing hormone therapy to older women who were at very high risk of heart disease. In fact, these women did not receive heart benefit from estrogen therapy and may even have suffered harm. Unfortunately, the findings in older women were extrapolated to newly menopausal healthy women who tended to have a favorable benefit to risk ratio with HT."

At least 70% of newly menopausal women have hot flashes and/or night sweats, and about 20% have moderate-to-severe symptoms that disrupt sleep and impair quality of life. Over the past 10 years, research from the WHI and other studies has provided a critical mass of evidence for the timing hypothesis, which suggests that younger women closer to the onset of menopause tend to have better outcomes on hormone therapy than older women who are distant from menopause onset. The younger women are also more likely to have hot flashes and other menopausal symptoms, and thereby derive quality of life benefits. Manson said, "The recent findings highlight the importance of individualized care for women. The 'one size fits all' approach to decision making is no longer acceptable." Manson adds that it will also be important to understand whether different types and formulations of hormone therapy (such as

patches, pills or lower doses of hormones) will have a different balance of benefits and risks.

Provided by Brigham and Women's Hospital

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