



# WHI Update

October 1998

## WHAT YOU SHOULD KNOW ABOUT THE “HERS” STUDY

Thank you for participating in the Hormone Program of the Women’s Health Initiative (WHI). You are helping us to get answers to questions about heart disease, cancer and fractures. From time to time, results from new studies become available. It is our goal to keep you informed of these developments. We have prepared this fact sheet to keep you up to date about new medical information from another study and how it relates to your participation in WHI.

### What is HERS?

HERS stands for the Heart and Estrogen/ Progestin Replacement Study. This study was designed to look at the effect of hormone replacement therapy on the rate of recurrent heart problems in women who already had heart disease.

### How is WHI different from HERS?

HERS is very different from the WHI. In all, HERS had 2,763 participants, while the WHI Hormone Program has over 27,000 women.

The HERS study included only women who had previous heart disease. The WHI Hormone Program includes women with and without previous heart disease. HERS also studied only estrogen and progestin in women who still had their uterus. The WHI Hormone Program is studying either estrogen and progestin or estrogen alone based on whether women do or do not have a uterus. Thus, less than 2% of the WHI Hormone Program participants would possibly have qualified for HERS.

The WHI Hormone Program is looking at the long-term effects (up to 12 years) of hormones on heart disease and many other health problems (for example, fractures, breast and endometrial cancers). HERS

followed participants for only 4 years on average, which was not long enough to study some of these other health problems. The WHI as a whole will answer many other important questions including the effect of diet on breast and colon cancer or the effect of calcium and vitamin D on fractures and colon and rectal cancer. Many WHI Hormone Program participants are taking part in these other WHI programs as well.

### What did the HERS trial show?

The HERS trial found that taking estrogen plus progestin for up to 4 years did not prevent further heart attacks or death from previous heart disease in postmenopausal women who already had a previous heart attack or known heart disease. This neutral finding occurred even though there was a good effect of treatment on cholesterol.

For the entire four-year HERS trial period, there were no significant differences in heart problems between the active hormone and the placebo groups. In the first year of HERS, the active hormone group did have somewhat more heart problems than the placebo group, but after 2 or more years the active hormone group had somewhat fewer heart problems.

As expected, HERS did show that women taking active hormone had an increase in problems with blood clots and a small increase in gallbladder disease. We have previously informed you of these risks of hormone therapy. Long-term studies like the Women's Health Initiative are needed to more fully understand both the short and long-term effects of estrogen on heart disease, and to learn how the overall benefits and risks of hormone replacement therapy balance out.

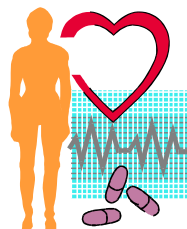
### **How do the HERS findings affect my participation in WHI?**

In sum, the HERS findings do not change the importance of WHI or the importance of your ongoing participation in the program. HERS has taught us about the 4-5 year effects of starting hormones in women who already have heart disease. The vast majority, about 98 percent, of the women in WHI do not yet have heart problems. WHI is crucial for providing answers about

whether hormones prevent heart disease in healthy women.

For women with known heart disease, the HERS investigators do not recommend that these women start hormones to prevent future heart problems. However, for women with heart disease who are already on hormones, the HERS investigators recommend that they could continue the hormones. This is because of the possible benefit after longer treatment. Similarly, the WHI investigators recommend that you continue if you are already in the WHI Hormone Program, so that we can learn more about the long-term effects of hormones.

Following publication of the HERS results, there is widespread agreement that there is a critical need for WHI and other randomized trials of hormones to give us more complete answers about long-term effects on women's health. You are helping us to find those answers, and your ongoing participation in the WHI Hormone Program is more important than ever!



**If you or your doctor have questions about this information, please contact the WHI clinic at:**

**Thank you for continuing to be a part of the WHI!**