What's New in WHI

The Women's Health Initiative Extension Study is now in the third year of data collection. What we're learning about women's health from WHI participants continues to impact women around the world, which is demonstrated by the hundreds of newspaper, magazine, and television reports on WHI findings that have occurred in the past few years. As of November 2007, 233 papers on WHI results had been published in scientific journals — one of the most respected sources of information for health care providers and scientific researchers. In addition, over 100 ancillary studies of WHI participants had been funded, with many more being proposed. An ancillary study involves collecting additional data or analyzing the blood samples provided by WHI participants to learn more about a specific topic that is not already part of the main WHI study. A few examples of the ancillary topics that WHI researchers are studying are genetic predictors of hypertension, neighborhood characteristics and the risk for heart disease, and decision making about cancer screening, as well as many, many others. Findings from these studies will add to the growing body of knowledge being generated by WHI participants.

You should feel proud knowing that you've made a permanent contribution that will be felt by women around the world for years to come!

Latest Findings from WHI

WHI scientists continue to study and publish reports on the data collected from WHI participants, including those in the original study and those who joined the Extension Study. You have probably seen many reports on WHI in the news over the years and will continue to do so in the future. Below is a summary of some of the findings reported in the past year.

Hormone Therapy and Risk of Cardiovascular Disease

(Journal of the American Medical Association, April 2007)

The two major reports published in 2002 and 2004 on the WHI Hormone Trials of estrogen-alone and estrogen-plus-progestin showed that hormone therapy does not reduce the risk of heart attack and increases the risk of stroke. Other WHI publications have suggested possible heart benefits in women aged 50-59 or for those who started hormone therapy less than 10 years after menopause. However, these findings were not "statistically significant."
WHI researchers have published a new analysis of the combined data from the two Hormone Trials to bring the effects by years since menopause into sharper focus. This combined analysis suggests that:

1. Risk of heart attack from hormones may not be increased in women who start the hormones less than 10 years after menopause, but there is increasing risk in women who are more distant from menopause

2. Risk of stroke from hormones does not depend on when a woman starts hormone therapy; strokes are increased regardless of years since menopause

3. Risk of death from any cause appeared to be reduced in women who were 50-59 years at the time they started hormones in the two WHI trials

The increased risk of heart attack in older women appeared to be concentrated in a small percentage (12-17%) of women with persistent hot flashes or night sweats, in part because those women had more risk factors for heart disease (such as high blood pressure, high blood cholesterol, diabetes, and overweight). This increased risk of heart attack did not apply to younger women with hot flashes or night sweats. These findings may be somewhat reassuring to women who are close to menopause and considering short-term hormone therapy to treat hot flashes or night sweats. These women do not appear to be at increased risk for heart disease if they take hormones, but they should check their risk factors, especially blood pressure, to avoid the increased risk of stroke. Women using hormones should also have regular mammograms, because the risk of breast cancer while on estrogen-plus-progestin is increased, even for those women who are less than 10 years after menopause.

Women who are more distant from menopause, however, should be very cautious about using hormone therapy. They have an increased risk of both heart attacks and strokes. If they have hot flashes or night sweats, they should be particularly careful about having their risk factors checked and treated.

This new, combined analysis from the WHI hormone trials does not change the current recommendation that hormone therapy should not be used for prevention of heart attacks. If hormones do not increase risk of heart attack at younger ages — and even if they reduce risk in these age groups — there is no certainty that any benefit will persist with long-term use into older ages.

Calcium/Vitamin D Supplementation and Weight

(Archives of Internal Medicine, May 2007)

Some research suggests that calcium and vitamin D may play a role in weight management. These nutrients may stimulate the breakdown of fat cells and suppress the development of new ones. WHI researchers looked at weight change in 36,282 participants over the 7 years they were in the WHI Calcium and Vitamin D Study (CaD). They found that at the end of the study, women in the group taking study pills with active calcium plus vitamin D weighed an average of 0.28 pounds less than those taking the placebo pills, which is a small but statistically significant difference in weight change.

Women taking active pills were also less likely to gain weight. The greatest benefits were seen in women whose total calcium intakes at the start of the study were below 1,200 mg/per day, which is the current recommended dietary intake for women this age. In these women, when compared to women taking placebo, women taking the calcium and vitamin D supplements had a lower risk of gaining weight, and had a higher likelihood of maintaining a stable weight (within 2.2 pounds of their starting weight) or losing
weight (more than 2.2 pounds), after three years in the study.

Prevention of weight gain is an important public health goal. Monitoring calories in the diet and maintaining daily physical activity should clearly be considered the basic parts of weight management. However, further research is needed to look at the effect of calcium supplementation, combined with caloric restriction and physical activity, on preventing weight gain.

Low-Fat Dietary Pattern & Ovarian Cancer
(Journal of the National Cancer Institute, Oct. 2007)
Recently published findings from the WHI Dietary Study suggest that a low-fat dietary pattern may reduce the occurrence of invasive ovarian cancer among postmenopausal women. These findings are the first to show a statistically significant health effect from the WHI low-fat dietary pattern. In the WHI Dietary Study, there were 160 cases of ovarian cancer reported among the 48,835 participants during the 8.1 years of the study’s intervention phase. There were fewer new cases of ovarian cancer identified among the dietary change (intervention) participants than among the usual diet (comparison) participants.

During the first four years of the Dietary Study, no effect of diet on ovarian cancer was seen, which was not surprising, since it can take years to see the effect of a preventive intervention on cancer risk. However, after the first four years of the study, there was a statistically significant 40% risk reduction in ovarian cancer among participants in the low-fat dietary change group compared to the usual diet group. The greatest reduction in cases of ovarian cancer was among dietary change participants who started with higher intakes of total fat as a percentage of calories and made the greatest reductions in fat intake. The reduced risk of ovarian cancer among the dietary change group compared to the usual diet group did not appear to be affected by the modest weight loss experienced by the dietary change group or by family history of ovarian cancer.

Among US women, ovarian cancer is the seventh most common cancer and the fifth leading cause of cancer death. While ovarian cancer is a rare form of cancer among women, the mortality rate is high, due to a lack of screening tools for ovarian cancer and because the symptoms are usually not obvious in the early stages of the disease. Data provided by WHI participants is helping scientists investigate the role of a low-fat diet in chronic diseases such as ovarian cancer in postmenopausal women.

Factors to Help Predict Risk of Hip Fracture
(Journal of the American Medical Association, Nov. 2007)
Hip fractures are associated with a high rate of illness, mortality, and cost. Using data from WHI participants, researchers evaluated clinical risk factors for hip fracture in postmenopausal women to create a model that would help predict the 5-year risk of hip fracture. The study included data from the 93,676 women in the WHI Observational Study (OS). Several factors were identified that were predictors of hip fracture in OS participants, which were then validated using hip fracture data on the 68,132 WHI clinical trial participants. During an average follow-up of 7.6 years, 1,132 hip fractures were identified among OS women; during an average follow-up of 8.0 years, 791 hip fractures occurred among clinical trial participants.

Eleven factors were identified that were predictive of hip fracture within 5 years. These factors were age, self-reported health, weight, height, race/ethnicity, self-reported physical activity, history of fracture after age 54, parental hip fracture, current smoking, current corticosteroid use, and treated diabetes.

Prevention of hip fracture is a high priority for patients, physicians, and public health. Using these variables to predict the 5-year risk of fracture may help patients and physicians make informed choices about possible lifestyle changes and/or medical interventions that might prevent hip fracture.
Finding Health Information on the Web

These days it's more and more common for people to search the internet for anything and everything — from what stereo equipment to buy to how to find a good plumber. However, when it comes to searching for health information on the Web, it is especially important to only consult sites that have reliable, accurate, and up-to-date information. Your first source of health information should be your health care provider, but often this can be supplemented with information from the internet.

When you research a topic on the internet, here are some questions that will help you evaluate the reliability of the information you find:

- **Who produces the website?**
  Sites run by the Government or by universities, or professional medical and health organizations are usually the most reliable sources for health information. The sites that are generally most reliable end in “gov, edu, or org”, which means that they are government organizations, universities, or nonprofit groups that focus on research and education.

- **Who is the intended audience?**
  Websites are designed for different audiences, for example, some are written for health professionals, some for children, and some for patients. If the information is too broad, too narrow, too simple, or too complex, it will not be useful.

- **Who wrote the material?**
  Review information on the site to confirm that the content is provided and/or reviewed by experts in the field who have the appropriate credentials. Any medical facts or tables should cite the original source of the information.

- **What is the purpose?**
  Try to determine the purpose and sponsor of the site, to ensure that the information is objective. Be wary of sites that seem to be selling a product or trying to get you to join their organization - the information may be written in a way to convince you to follow their point of view.

- **How current is it?**
  Check to see if the information has been updated recently; the date can sometimes be found at the bottom of the page. Because health information changes quickly, it's important to know that any new findings are included.

**Hot Tip!**

If you're interested in accessing the internet, but don't know how, you may want to check with your local library. Most public libraries have computers you can use for free, and staff who can assist you in getting connected to the internet. Also, if you still have copies of previous issues of the WHI participant newsletter on hand, see WHI Matters, Vol. 10A (2004) for information on getting connected to the Web. Once you're connected, be sure to visit the WHI participant website at www.whi.org.
Recommended Consumer Health Websites

Visit the Medical Library Association's website at http://www.mlanet.org/resources/userguide.html for their list of the most useful consumer health websites and tips for evaluating the information you find on the Web. Here are some of the sites they recommend:

- National Heart, Lung and Blood Institute (NHLBI) www.nhlbi.nih.gov
- The National Cancer Institute www.cancer.gov
- Centers for Disease Control and Prevention www.cdc.gov
- www.WebMD.com
- American Academy of Family Physicians www.familydoctor.org
- Mayo Clinic www.mayoclinic.com
- Medem www.medem.com

Health HOTLINES

Even if you are unable to access the internet, there are still many sources for health information. The following toll-free numbers offer reliable, free health information, including publications and referrals to local services.

Dial 1-800...

Alzheimer's Association ................... 272-3900
American Cancer Society ................ 227-2345
American Diabetes Association ........... 232-3472
American Dietetic Association .......... 366-1655
American Heart Association ............ 242-8721
American Liver Foundation ............... 223-0179
Arthritis Foundation ....................... 283-7800
Cancer Information Service .............. 422-6237
Eldercare Locator ......................... 677-1116
Mental Health America ................... 969-6642
National Council on Aging ............... 424-9046
National Council on Alcoholism ........ 622-2255
National Headache Foundation .......... 843-2256
National Osteoporosis Foundation ..... 223-9994
National Stroke Association ............ 787-6537

Letters

We'd love to hear feedback on the newsletter. We regret that we cannot answer questions about individual medical conditions. Send a letter to:

WHI Matters
Fred Hutchinson Cancer Research Center
1100 Fairview Ave N, M3-A410
P.O. Box 19024
Seattle, WA 98109

Staff Information

WHI Matters is produced by the WHI Coordinating Center at the Fred Hutchinson Cancer Research Center.

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Our Answers to Your WHI Questions

WHI participants often send us letters reporting stories of recent adventures, important events in their lives, and changes in their health. These letters often ask questions about various aspects of participation in WHI. We love to hear about your experiences and appreciate that you take the time to share with us. While we regret that we can’t respond to individual letters, we will try to answer some of the more commonly asked questions here.

Q I recently received a second packet of forms to complete. I already completed and mailed back the first packet of forms. Did you receive it? Why am I receiving a second packet? Do you want me to complete them, too?

A If you have recently completed and mailed back a packet of forms, you do not need to fill out a second set. We are processing and mailing thousands of packets each month to women all over the country, so packets will sometimes cross in the mail.

Q I just returned home from a long trip and found the forms you sent. Do you still want me to complete them?

A Yes, we are always interested in receiving your health information. If you have not completed any WHI forms for awhile, either by mail or phone, then it would be appropriate to complete and mail them back. If you received two sets of forms while you were gone, it is only necessary to complete one set.

Q I want to report an address change. OR: I have a question about how to complete an item on one of the study forms I received in the mail. Who should I call when I need help completing my forms, or if I have a question about the study?

A You should call your local WHI clinical center at the number located on the cover letter in your data collection packet, and listed on the back of the newsletter. There are staff members at your clinical center who would be happy to answer your questions, talk with you about any concerns, or help you complete your forms.

Q I loved reading about the WHI Legacy Conference that was described in the last issue of WHI Matters, but I’m very disappointed that I didn’t get to attend.

A While the group of WHI participants as a whole was the focus of the celebration, it was not feasible to hold a celebration that could include all 160,000 participants, as much as we would have enjoyed such an occasion! The purpose of this conference was to celebrate the legacy of the WHI, and to help health care providers and representatives from national newspapers, magazines, and organizations recognize the major contributions made by the women in this important study. Clinics in the Washington DC area, where the celebration was held, were able to invite only a random selection of participants from the area to attend. A videotape of the conference can be viewed on the participant website at www.whi.org.

Q If I misplace the packet of forms that you send, can you send me another set?

A If we do not receive the packet of completed forms back from you within a few months after we mail the first packet, a second packet will be automatically sent to you.
**I may be moving to a nursing home soon and my daughter has offered to help me out with my WHI forms after I move. Is this okay?**

**A** Yes, in fact we encourage participants to name a family member or friend who can serve as a “proxy” for them in the study. A proxy is someone who can “stand in” for you and tell us about your health when you cannot because of serious illness. Even if you do not need a proxy now, it is a good idea for you to provide your clinical center with the name of a proxy; in case one is needed in the future. We also encourage you to remind the people you currently live with about your commitment to the WHI. Sometimes WHI staff will call or send a mailing to a participant’s home, and it’s important that other members of the household realize that it’s not “junk mail” or a sales call.

**I don’t have cancer. Why are my forms sent from a cancer research center (i.e., the Fred Hutchinson Cancer Research Center - FHCRC)?**

**A** The FHCRC, located in Seattle, Washington, is the Clinical Coordinating Center for the WHI. All WHI forms are mailed to and from the coordinating center for data entry and analysis. Even though the forms are sent to Seattle, the local clinical centers are still able to access the data provided by their own center’s participants. Because there are no interventions or annual visits during the Extension Study, staffing at the local clinical centers is much lower than it was previously. It is more cost-efficient and timely for the WHI Extension Study mailings to occur from a central location.

**I’ve noticed that the pencil wasn’t included in the packet of forms I just received in the mail. Is this a mistake?**

**A** No, we are no longer including pencils in the mailed packets. Because of recent changes in procedures at the US Postal Service, we are no longer able to include the pencils without paying a substantial fee to cover the handling of packets with enclosures that do not fit through the automated machines at the Post Office. We apologize and hope this does not cause a major inconvenience to our participants.

**I already signed a medical release form. Why do I need to sign a new form?**

**A** For many hospitals and doctor’s offices, the medical release form is only valid for a certain length of time, for example, one year. If you have several health events that we need additional information about, we may ask you to sign one or more medical release forms to cover various time periods and health care providers, as part of their requirements.

**I’m interested in knowing what’s new with WHI.**

**A** We try to keep you up-to-date on major WHI findings in your annual issue of this newsletter. To access information about WHI on more frequent basis, please visit the WHI participant website at www.whi.org. There you’ll find summaries of study findings, copies of previous newsletters, and answers to common questions.
Stay In Touch

Don't forget to call your local Clinical Center if your address or phone number changes!

Albert Einstein College of Medicine
Bronx, New York • (718) 931-1010

Arizona Prevention Center
Phoenix, Arizona • (602) 341-7672
Tucson, Arizona • (520) 321-7440

Baylor College of Medicine
Houston, Texas • (713) 798-4033

Berman Center for Clinical Research
Minneapolis, Minnesota • (612) 341-7921

Brigham and Women's Hospital
Boston, Massachusetts • (617) 732-3124

Center for Health Research
Salt Lake City, Utah • (801) 585-5100

Charlton Memorial Hospital
Fall River, Massachusetts • (401) 729-2865

Detroit Clinical Center
Detroit, Michigan • (313) 966-8000

Emory University
Atlanta, Georgia • (404) 370-7355

Evanston Hospital
Evanston, Illinois • (312) 908-5790

Fred Hutchinson Cancer Research Center
Seattle, Washington • (206) 667-6551

The George Washington University
Washington, DC • (202) 741-2323

Kaiser Permanente—Bay Area Clinic
Oakland, California • (510) 891-3201

Medical College of Wisconsin
Milwaukee, Wisconsin • (414) 805-7040

Memorial Hospital of Rhode Island
Providence, Rhode Island • (401) 722-2865

Nevada Clinical Center
Reno, Nevada • (775) 794-4906

New Jersey Medical School
Newark, New Jersey • (973) 972-2944

New Brunswick, New Jersey • (732) 235-6546

Northwestern University
Chicago, Illinois • (312) 951-0810

Ohio State University
Columbus, Ohio • (614) 688-3563

Rush-Presbyterian St. Luke’s Medical Center
Chicago, Illinois • (312) 553-2209

Stanford Women's Health Initiative
San Jose, California • (650) 725-5307

Stony Brook Clinical Center
Stony Brook, New York • (631) 444-9800

South Bay WHI Program
Torrance, California • (310) 222-2217

UBC Preventive Medicine
Vancouver, British Columbia • (604) 827-4289

UCLA Women's Health Initiative
Los Angeles, California • (310) 629-9002

UMASS/Fallon Clinical Site
Worcester, Massachusetts • (508) 856-5452

University at Buffalo
Buffalo, New York • (716) 825-3212

University of California, Davis
Sacramento, California • (916) 734-5562

University of California, Irvine
Irvine, California • (714) 456-8858

University of California, San Diego
Chula Vista, California • (858) 514-0325
La Jolla, California • (858) 514-0325

University of Cincinnati
Cincinnati, Ohio • (513) 584-6061
or (855) 558-6062

University of Florida
Gainesville, Florida • (352) 392-1920
Jacksonville, Florida • (352) 392-1920

University of Iowa
Davenport, Iowa • (800) 344-3515
Des Moines, Iowa • (515) 241-8989

Iowa City, Iowa • (800) 814-9535

University of Miami School of Medicine
Miami, Florida • (305) 243-4800

University of North Carolina
Chapel Hill, North Carolina • (919) 966-3155

University of Pittsburgh
Pittsburgh, Pennsylvania • (412) 624-3958
(800) 552-8140

University of Wisconsin
Madison, Wisconsin • (608) 261-1867

UT Health San Antonio, Texas • (210) 567-1850

UT Prevention Center
Memphis, Tennessee • (901) 448-6405

WHI of the Nation's Capital
Washington, DC • (202) 675-4770

WHI of the Tidewater
Greensboro, North Carolina • (336) 716-2243
Winston-Salem, North Carolina • (336) 716-2243

Women's Health Hawaii
Honolulu, Hawaii • (808) 441-5555

If you have any questions about the WHI Extension Study, or if your address or phone number changes, please call your WHI clinic at the number listed above. If you have moved to a new area, you should contact the center where you originally joined the study. There are still WHI staff on hand at your clinical center to record address changes and answer your questions. Thank you!