



WHI EXTENSION STUDY

Matters

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OF THE
ANSWER

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THE WOMEN'S HEALTH INITIATIVE just celebrated its 20 year anniversary, with over 93,500 women still participating in the WHI Extension Studies! Each year these women continue to provide health updates by mail. These updates are essential to what we're learning about women as they age, so we truly appreciate the commitment of each and every participant. By mid-2014, over 1000 papers using information provided by WHI participants had been published!

This remarkable contribution to women's health is only possible because of your continued dedication to the study.

Many participants have also participated in "ancillary" studies, which are additional studies that supplement what we are already learning in WHI. These extra studies focus on a wide range of women's health issues, from cognitive functioning and dementia to the impact of air pollution and other environmental characteristics on women's health. While many of the WHI ancillary studies have been completed, new studies are starting all the time. For example, a new trial will soon be looking at the impact of

cocoa and multivitamin supplements on cardiovascular disease and cancer. Here are updates on two ongoing ancillary studies, which we introduced in the last newsletter:

Physical Activity Study – Women were invited to join this study as part of the Long Life Study conducted during 2012-2013. In this study, women wore

Ancillary studies focus on a wide range of women's health issues, from cognitive functioning and dementia to the impact of air pollution.

a "pedometer" for one week to measure their physical activity, filled out a Sleep Log and Physical Activity Questionnaire, and reported their falls

each month on a calendar. Enrollment in this study was completed in early 2014, with over 7000 participants. While most of these participants have finished all aspects of their participation, many are still in the process of tracking their falls for a year. WHI researchers will learn an enormous amount of information about the impact of various levels of physical activity on a woman's health and about types of injuries and other details associated with falling.

Continued on p. 2



- 2** The Importance of Your Health Updates and Medical Records
- 3** Focus on Findings
- 6** Creating a MedInfo Form for Emergencies
- 8** Center Information

INSIDE THIS ISSUE



Continued from cover

Life and Longevity After Cancer (LILAC) Study

– This ancillary study is exploring how different types of cancer and cancer treatments may affect women’s health and well-being. The LILAC study has consented approximately 6,500 women diagnosed with certain types of cancer, including breast cancer, colorectal cancer, endometrial cancer, ovarian cancer, lung cancer, melanoma, lymphoma, and leukemia. In the fall of 2013, WHI participants who have had a diagnosis of one of these cancers were invited by mail to join the LILAC study. The women in the study completed forms and gave researchers permission to collect medical records and tumor tissue related to their cancer. This information is being used to learn more about cancer treatments and how they affect a woman’s short-term and long-term health after cancer. The stored tumor tissue and information about treatment and treatment effects will be available for future research.



The Importance of Your Health Updates and Medical Records

WHI PARTICIPANTS sometimes ask if they should continue to complete their medical history updates if their health does not change or starts to decline. The answer to that is a resounding yes; we are always interested in receiving updates about your health! The answers to questions that participants have been asked since the beginning of the WHI may be linked to health outcomes later in life. WHI scientists use these answers to learn which aspects of a woman’s health history and behavior are related to her medical outcomes later in life. Scientists can only study those relationships if they receive health information from women over time and as they age.

To enhance our understanding of the major health issues facing women as they get older, we collect medical records for specific health events such as heart disease, stroke, cancer, hip fracture, and overnight hospital stays. If one of these specific events occurs and is reported on the annual health update, we may contact the participant or her proxy for permission to review the medical records related to that specific event. If you have experienced one of these events, such as a broken hip, you are already familiar with this process. Sometimes, a woman is unable to complete this information herself, for example, due to changes in her vision. In those cases, most WHI participants call their Regional Center for help or ask a family member or friend (proxy) to provide the information for them.

Sadly, it is sometimes the case that a participant reports one of these health events on her annual medical history update, but then dies before she is able to sign a medical authorization to obtain the medical records related to that event. When this happens, we try to contact the proxy or next of kin

Thank you to those women who have contributed their participation in the LILAC study! We truly appreciate all that you have done for this important research. Here are a few comments that LILAC women have shared with us:

- *“Thank you for your follow-up—it is very important for future generations of women.”*
- *“Cancer is a wake-up call to look at our life and to make the changes that lead to a richer, deeper, purpose-filled and balanced life.”*
- *“I wouldn’t have wished for cancer, but it gave me a whole new appreciation for life, friends, and family.”*
- *“Breast cancer did not/does not define me. It was what I had, not who I am.”*
- *“Keep up the invaluable research! I am very pleased to be a part of this and seem to be A-OK after my cancer radiation!”*



to receive permission to obtain these records. If the proxy declines access, we do not request the medical records. If given permission by the proxy or next of kin, we only collect medical records for the health events that WHI follows (that is, those listed above).

However, there are situations when we are unable to reach the proxy to receive written consent. This occurs if the proxy cannot be located, is deceased, or provides verbal consent over the phone, but does not return the signed medical release form. In these rare cases, we may still send a request to your health care provider to review your medical records, but again, we would only request those records that were related to the health event reported on your annual health update. No other medical records would be requested

or reviewed. All medical records collected are accessible only to WHI researchers and all personally identifiable information is blacked out to protect the privacy of you and your family. It is important to discuss your participation in WHI with your

proxy (child, spouse, other family member, close friend) and to let them know they **may** be contacted by WHI for information and permission to release medical information.

We realize this is a complex and sensitive topic. If you have

any questions or concerns about this specific issue, please call us at the WHI Clinical Coordinating Center: 800-218-8415. Also, if you change your address or phone number, please give us a call to ensure that we have updated information for you and your proxy.

It is important to discuss your participation in WHI with your proxy—a child, spouse, other family member, or close friend.

Letters: We love to hear feedback on the newsletter. We regret that we cannot answer questions about individual medical conditions.

Send letters to:

WHI Matters

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Focus on Findings



AS OF JUNE 2014, over 1000 papers based on WHI data have been published in scientific journals! The number of papers has grown each year since the start of WHI, to a high of 142 publications in 2013. The number published in 2014 may be even higher, with new papers covering a wide variety of topics being written each month. Here are some examples of new papers that researchers are currently working on:

- Pet ownership and risk of cardiovascular disease
- Physical activity during childhood and risk of Alzheimer's disease
- Impact of state-level tobacco controls on smoking status
- Distribution of breast cancer cases by rural/urban areas
- Geographic differences in cognitive decline and dementia risks
- Diet quality, bone mineral density, and bone fractures

The following summaries highlight a few of the papers published in the past year. You may have read about some of these in your local newspaper or on the internet, as many of them made a big splash in the news.

Continued on page 4



FOCUS ON FINDINGS

Continued from page 3

■ Global Paper on Hormone Trial Findings

(Journal of the American Medical Association, October 2013)

WHI investigators, led by Dr. JoAnn Manson, recently published a comprehensive article on the overall findings of the two WHI hormone trials. Although most of these results had been previously published, they appeared scattered in nearly 120 papers. These prior reports were generally more focused, showing the effects of one of the two types of hormones tested on a specific disease or health condition. In this article, for the first time, WHI presented all of the major health effects of hormone therapy in one document, with side-by-side comparisons of Estrogen-plus-Progestin (E+P) and Estrogen-Alone (E-Alone) for cardiovascular disease, cancers, fractures, diabetes, gall bladder disease, and several quality of life measures, both during the trials and several years after participants stopped taking study hormone pills. The paper also gave results by age group at time of WHI enrollment. While the risks and benefits for each of the diseases varied depending on whether E+P or E-Alone were used, the overall conclusion for both treatments continues to be that the risks outweigh the benefits and neither E+P or E-Alone should be used for disease prevention.

■ Obesity and Survival

(Journal of American Medical Association Internal Medicine, November 2013)

Eileen Rillamas-Sun, PhD and other WHI researchers studied the link between obesity and survival to 85 years or older without major chronic disease or disability. Specifically they looked at body mass index (an index that includes height

and weight) and waist measurement in over 36,000 women in the Observational Study and Clinical Trials. They classified these women into five groups: healthy (survived to age 85 without major chronic disease or mobility disability), prevalent disease (survived with one or more major chronic disease at baseline but without new disease or disability), incident disease (survived and developed one or more major chronic disease during study follow-up), disabled (survived and developed mobility disability), and died. They found that compared with healthy-weight women, underweight and obese women were more likely to die before 85 years of age. Overweight and obese women had higher risks of incident (new) disease and much higher rates of disability. A high waist circumference (greater than 34.6 inches or higher) was also linked to higher risk of earlier death, disease, and disability. In summary, being obese makes it less likely that a woman will reach the age of 85; for those who reach age 85, obese women are more likely to have a chronic disease or mobility problem than non-obese women.

■ Physical Activity and Mortality

(American Journal of Preventive Medicine, February 2014)

Based on evidence that less sedentary time (i.e., inactive time spent sitting or lying down) can provide health benefits, Rebecca Sequin, PhD and her WHI associates looked at the relationship between sedentary time and cardiovascular disease, heart disease, and cancer mortality in 92,234 women enrolled in the WHI Observational Study. Using data provided in WHI questionnaires, they divided sedentary time into four categories (4 or less hours, 5-8 hours, 9-11 hours, 11 or more hours per day) and controlled for physical function (i.e., ability to perform basic physical activities) and physical activity levels when conducting the data analysis. Compared with women who had the least sedentary hours, women who had the highest



sedentary hours had an increased risk of mortality (death) overall and an increased risk of death from cardiovascular disease, heart disease, and cancer mortality. Because sedentary time tends to increase as we age, health interventions should focus on ways to encourage activity and discourage the amount of time spent sitting and lying down.

■ Economic Return from the E+P Trial

(Annals of Internal Medicine, May 2014)

In 2002, WHI Investigators released findings from the WHI Estrogen-plus-Progestin (E+P) Trial showing that the risks from using E+P hormone therapy outweighed the benefits. These findings led to a huge reduction in the use of this type of hormone therapy among postmenopausal women. Until now, the economic effect of this change has not been studied.



Joshua Roth, PhD

WHI investigators, led by Joshua Roth, PhD, looked at the economic impact the E+P findings have had in the United States between 2002 and 2012. To do this, they created a mathematical model that looked at health outcomes and economic costs related to two possible scenarios 1) the “WHI scenario,” which looked at what has happened since the release of the results, and 2) the “no-WHI scenario,” which projected what might have happened if the WHI had not occurred. The model estimated disease rates, disease costs, and health-related quality of life for each of the two scenarios. In terms of hormone therapy use, the model estimated that 5.2 million women used hormones in the WHI scenario, and 9.5 million women would have used hormones in the no-WHI scenario (i.e., an additional 4.3 million women would have used E+P hormones if the WHI results had not occurred).

When taking the estimated health costs and outcomes from the two scenarios into account, the model showed that the WHI scenario, when compared with the no-WHI scenario, resulted in a \$35.2 billion savings in direct medical costs (measured in 2012 dollars). These savings were mainly due to fewer women buying hormone pills and the decrease in rates of breast cancer and cardiovascular disease resulting from the reduction in hormone use. In the no-WHI scenario, while it was estimated that there would have been fewer bone fractures and fewer cases of colorectal cancer than in the WHI scenario, the cost savings from the reduced cases of breast cancer and cardiovascular disease in the WHI scenario were much greater. The investigators also calculated health-related quality of life for each scenario and found that the increase in quality adjusted life years associated with decreased rates of breast cancer and cardiovascular disease was greater than the decrease in quality adjusted years of life due to fractures.

The cost of conducting the WHI E+P trial, which was funded by the National Heart, Lung, and Blood Institute at the National Institutes of Health, was \$260 million. The goal of this paper was to look at the “return” on that investment, i.e., what did we get for all that time and money? When all costs and quality-adjusted years of life are considered, the total economic return of the WHI trial is an estimated \$37.1 billion! These findings suggest that investment in high quality trials of important topics may have a high rate of return in terms of public health and medical costs. This represents a return on all of the WHI participants’ investments of time, effort, and dedication. We want to again sincerely thank the thousands of women who made the WHI trials possible.

When all costs and quality-adjusted years of life are considered, the total economic return of the WHI trial is an estimated \$37.1 billion!



Creating a MEDinfo Form for Emergencies

WHI participant Louise Cate recently sent us this article describing an event in her life that led to the creation of a medical information form to be used by friends and loved ones in the event of an emergency. We thought this was a great idea (and a well-written story!) and are sharing it, with Louise's permission. Louise has been in the WHI for nearly 18 years, originally participating in the Dietary Study. She has 5 children and 22 grandchildren who have ancestors from Europe, Africa, Mexico, and 3 American Indian tribes. Nearly every day for the past 13 years, Louise has taken her German Shepard hiking in a nearby county park with friends from around the world. She and her husband love to garden and have created a beautiful backyard that is every child's dream, complete with a trampoline, tether ball, sandbox, and swing set. Here's her story:

The ringing of the telephone interrupted my preparations for breakfast. As I answered the phone, I glanced at the clock and wondered who could be calling at 7:30 a.m. "Louise, please come over!" It was my neighbor Joan's tenant, Tom, who sounded upset. "Joan is throwing up. She is shaking and seems to have a temperature."

I ran next door. Joan, my delightful 84-year old neighbor, was lying on top of her bed, shaking violently. I spread a sheet over her and checked her temperature. It was over 102 degrees. I didn't have any idea what was wrong with her, but I knew she was seriously ill. We called 911 immediately, and in a few minutes two fire engines and an ambulance were out front. Four large uniformed men entered. They shot questions at me. "What happened?" "Is she allergic to anything?" "What hospital should we take her to?" I had no answers.

Frightened by the seriousness of Joan's condition, I wondered where I could find the information they needed. I searched for Joan's purse. The questions



Louise and her husband Henry Pratt Cate, Jr. with their oldest grand-daughter, Jessica, and her husband Ryan

continued. "Do you have her Medicare card?" "Is she on any medications?" Neither Tom nor I could answer any of the questions, and Joan was too ill to help. I finally found Joan's purse and was able to give the attendants her Medicare card.

I followed the ambulance to the hospital, where the emergency admittance clerk asked me more questions. "What is Joan's full legal name?" "When was she born?" "Does she have any secondary insurance?" How could I know any of this stuff? Joan had been like a grandmother to my five children and one of my best friends for 33 years, but she seldom discussed her health. We usually discussed current events and psychology. "Has she been in this hospital before?" "What is her medical history?" "What is her social security number?"

After further examining Joan's purse, I found the answers to some of the questions. After seven hours in the emergency room, Joan was moved to a hospital room. The tentative diagnosis was viral pneumonia. When I visited Joan that evening, I brought her seven-day pillbox. Later Joan called and asked me to go to her home, check her pill bottles, and tell her the names of the pills she took, the dosages, and why she took the pills. The hospital needed to know.

The next day I created a "MEDinfo" form that contained all the information needed if I had to call



911 for Joan again. I made similar forms for my husband and myself, and made several copies for my purse, wallet, friends, and family members.

Recently I phoned Joan, who now lives in a retirement home in southern California. She said she had fallen earlier in the day and had to be taken to an urgent care facility. Before I had a chance to ask her how badly she was hurt, she began to tell me what happened when the nurse came in to treat her: "Louise, when the nurse started to ask me questions, I gave her the MEDinfo form you created for me. She was surprised and pleased to see all the answers to her questions. Another nurse came over to look at my MEDinfo form and asked

if she could make a copy of it. The doctor came in and asked what medications I was taking. The nurse waved the form at him and told him everything they wanted to know was on it. The doctor asked if the form was the result of some high tech program, but I laughed and told him my neighbor had made it for me."

I was delighted to hear Joan's doctor and nurse appreciated the MEDinfo form. I remember how pleased both the ambulance men and the admittance clerk at the hospital were with the form the last time I took Joan to the hospital, before she moved. Eventually I hope everyone will have a MEDinfo form. If I need to call 911, I'm prepared. Are you?

MEDinfo Form

Patient's Legal Name: _____

Gender: Male Female

Address: _____

Phone: _____

Date of Birth: _____

Social Security #: _____

Preferred Hospital: _____

Previously admitted to this hospital? Yes No

Medicare #: _____

Other insurance: _____

Primary Doctor: _____

Doctor's Phone: _____

Blood type: _____

Allergies to medications: No Yes

If YES, list: _____

Other allergies: No Yes

If YES, list: _____

Pacemaker: No Yes: Model # _____

Medical Directive: No Yes

If YES, where is it? _____

Current Medications: *(name, dosage, & purpose)*

- _____
- _____
- _____
- _____
- _____

Family and friends: *(relationship, names, & phone numbers of people to be informed)*

SPOUSE PHONE

SON PHONE

DAUGHTER PHONE

NEIGHBOR PHONE

FRIEND PHONE

Medical Problems

Date

- _____
- _____
- _____
- _____
- _____



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Stay in Touch } Please call your Regional Center if your address or phone number changes.



To locate your Regional Center, find the name of your WHI clinic center on the list below.
 The Regional Center and phone number for each center is shown in the right-hand column.

WESTERN REGIONAL CENTERS

Kaiser Permanente/Bay Area Clinic, Oakland, CA	Stanford University (650) 725-5307 (888) 729-8442
South Bay WHI Program, Torrance, CA	
Stanford University/San Jose Clinical Center, Palo Alto, CA	
UCLA Center for Health Sciences, Los Angeles, CA	
University of California, Davis, CA	
WHI-UC Irvine Clinical Center, Orange, CA	
Center for Health Research, Portland, OR	University of Arizona (520) 626-5487 (800) 341-7672
University of Arizona, Phoenix, AZ	
University of Arizona, Tucson, AZ	
University of Hawaii School of Medicine, Honolulu, HI	
University of Nevada, Reno, NV	
UC San Diego Clinical Center, Seattle, WA	Fred Hutchinson Cancer Research (800) 514-0325
Seattle Clinical Center, Seattle, WA	

MIDWESTERN REGIONAL CENTERS

Evanston Hospital (Northwestern University), Evanston, IL	Ohio State University (614) 688-3563 (800) 251-1175
Northwestern University, Chicago, IL	
Medical College of Wisconsin, Milwaukee, WI	
Rush-Presbyterian-St. Luke's Medical Center, Chicago, IL	
Ohio State University, Columbus, OH	
University of Cincinnati College of Medicine, Cincinnati, OH	University of Iowa (515) 643-4840 (800) 347-8164
Berman Center for Outcomes and Clinical Research, Minneapolis, MN	
University of Iowa, Davenport, IA	
University of Iowa, Des Moines, IA	
University of Iowa, Iowa City, IA	
University of Wisconsin, Madison, WI	
Detroit Clinical Center, Detroit, MI	Univ. of Pittsburgh (412) 624-3579 (800) 552-8140
University of Pittsburgh, Pittsburgh, PA	

NORTHEASTERN REGIONAL CENTERS

New Jersey Medical School, Newark, NJ	University at Buffalo (855) 944-2255 (716) 829-3128
UMDMJ – Robert Wood Johnson Medical School, New Brunswick, NJ	
Albert Einstein College of Medicine, Bronx, NY	
School of Medicine, SUNY, Stony Brook, NY	
University at Buffalo, Buffalo, NY	
Brigham and Women's Hospital, Chestnut Hill, MA	Brigham and Women's Hospital (617) 278-0791 (800) 510-4858
Charlton Memorial Hospital, Fall River, MA	
Memorial Hospital of Rhode Island, Pawtucket, RI	
UMASS/FALLON Women's Health, Worcester, MA	
George Washington University, Washington, DC	WHI of the Nation's Capital – Medstar (301) 560-2924
WHI of the Nation's Capital – Medstar, Hyattsville, MD	

SOUTHEASTERN REGIONAL CENTERS

UNC Women's Health Initiative, Chapel Hill and Durham, NC	Wake Forest University School of Medicine (336) 713-4221 (877) 736-4962
Women's Health Initiative of the Triad, Greensboro, NC	
Women's Health Initiative, Winston-Salem, NC	
University of Tennessee, Germantown, TN	
University of Tennessee – Medical Center, Memphis, TN	
Baylor College of Medicine, Houston, TX	University of Florida, Gainesville (352) 294-5211 (800) 944-4594
University of Texas Health Science Center, San Antonio, TX	
University of Alabama, Birmingham, AL	
Emory University, Decatur, GA	
University of Florida Clinical Center, Gainesville, FL	
University of Florida Clinical Center, Jacksonville, FL	
University of Miami School of Medicine, Miami, FL	

WHI CLINICAL COORDINATING CENTER

Fred Hutchinson Cancer Research Center, Seattle message line (800) 218-8415