



## WHI: Looking Back, Looking Ahead

**T**he very first woman joined the Women's Health Initiative (WHI) in October, 1993. By 1998, an incredible 161,808 women across the U.S. had joined the WHI, with 93,676 joining the Observational Study, and 68,132 enrolling in one or more of the three Clinical Trials: the Hormone Program, the Dietary Study, or the Calcium/Vitamin D Study. Together, these women have made WHI one of the largest studies of its kind ever done in the world. The results of these studies have changed the way women are cared for and will lead to improvements in their lives for many generations to come.

In 2004, when the intervention phase of the Clinical Trials was over, we invited the WHI women to join the WHI Extension Study, a five-year extension to the original phase of the study. Over 115,000 women agreed to continue in this phase of WHI, and have provided an additional 5 years worth of information on health and aging.

*continued, p. 2*

- 1** WHI: Looking Back, Looking Ahead
- 5** The Women of WHI: Then and Now
- 8** Focus on Findings
- 12** Center Information

INSIDE THIS ISSUE

**WHI is a one-of-a-kind study that will never be repeated.**





Over the past 17 years, as a WHI participant, you have answered hundreds of questions about your health and lifestyle habits. This questionnaire data, as well as the blood samples and other physical measures provided in the early years, have become a rich source for learning about the health of women as they age. From this resource, hundreds of articles have been published in scientific journals, and hundreds more are in progress. WHI has also been featured in hundreds of news articles and television programs. WHI has even been mentioned in a popular novel! There's no question that the women of WHI have made a major and lasting impression on the landscape of women's health around the world – rest

assured that your contributions will never be forgotten.

### **A Look Ahead**

The impact of WHI on women's health has been so important that WHI scientists and the National Institutes of Health would like to continue collecting health information from WHI participants. This information will help us answer additional questions about how women's health changes as they get older. Why is it important for WHI to continue? WHI is a one-of-a-kind study that will never be repeated. WHI offers a unique opportunity to study the health of women as they age, in a way that no other study has been able to do.

### **Women in WHI provide critical information that will help answer major questions about the course of aging and health, such as:**

- What are the health costs associated with aging?
- What are the most common illnesses and how do they affect a woman's quality of life?
- What are the risk factors for illness, and do they vary by race?
- How do environmental and genetic factors affect health?
- What does "healthy aging" look like, that is, what are the characteristics of women who live into their 90s and even 100s?
- What types of medications are women taking?

**WHI is in the best position to answer these types of questions based on the experiences of tens of thousands of women representing all races across the country.**



**Even though there are thousands of women in WHI, each and every woman's health experience is unique and cannot be replaced with information provided by any other woman.**

### **What's Next for You?**

In the next few weeks, you will receive an invitation to continue in The WHI Extension Study. This mailed invitation will include a consent form for you to sign and return. As a participant in this continued phase, you will be asked to continue to complete forms each year, exactly as you have in the past 5 years. If it becomes difficult for you to complete the mailed forms by yourself, you are welcome to complete the forms by telephone, or with the help of someone you know and trust.

If you decide to continue with WHI, the WHI Clinical Coordinating Center in Seattle will mail you the forms each year, at around the same time you've received them in the past. If we need additional details, we will call you and ask your permission to obtain medical records from your health care provider, if needed.



This year marks a transition for WHI data collection. In the past, your local clinical center has been responsible for phone contacts and for obtaining medical records. To streamline this process and to reduce costs nationwide, this follow-up will now be done by either the Clinical Coordinating Center or by one of a few WHI Regional Centers or their affiliates. These Regional Centers will be selected from the original group of 40 WHI Clinical Centers to assist in this process.

We hope you will agree to continue with us in the next phase of WHI. It is important for us to learn about all women, including those who experience health problems, as well as those who don't. Even though there are thousands of women in WHI, each and every woman's health experience is unique and cannot be replaced with information provided by any other woman.



### The Future of WHI

Taken individually and as a whole, you and the other WHI participants are a fascinating, diverse set of women who have already accomplished what many thought couldn't be done. The number of women who joined WHI and who continue to contribute to the study is truly astonishing, and we are honored to be working with such a group of dedicated, amazing women. If you decide to continue with us in the WHI Extension,

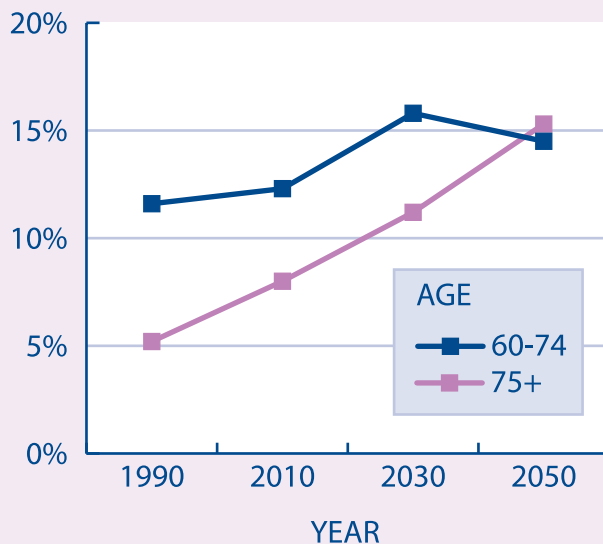
we look forward to working with you in the future. If you decide not to extend your participation we understand, and thank you for all you have already contributed. Each of you has been truly important in helping to understand health issues of concern to postmenopausal women. Women around the world owe a tremendous thanks for your dedication over the years. You will always be part of the answer!

## OUR AGING POPULATION

You may have heard that the U.S. population is aging. What exactly does that mean, and what does it look like? Here are a few trends noted by the National Institutes of Health and U.S. Census:

- The U.S. population aged 65 and over is expected to double in size in the next 25 years
- By 2030, almost 1 out of 5 Americans — 72 million people — will be 65 years or older
- People 85 and over are the fastest growing segment of the U.S. population.

This chart shows the percentage of people in the U.S. aged 60-74 and 75+ in 1990 and 2010, and what it is expected to be in the years 2030 and 2050.



There are several reasons why a greater proportion of the population is older in age, including the post-WWII baby boom, as well as a major increase in the average life span during the second half of the 20th century. The growing number of older adults will increase the need for medical and social services, increasing health and long-term care costs. To help respond to this growth, studies like WHI, which provide much-needed information about people as they age, are more important than ever.





## The Women of WHI: Then and Now

**I**n 2005, an amazing 115,406 of the original WHI participants agreed to join the Extension Study through 2010, providing an additional 5 years worth of data on health and aging. A lot has changed in the seventeen years since the start of the study in 1993. How have our women changed? Here are a few comparisons.

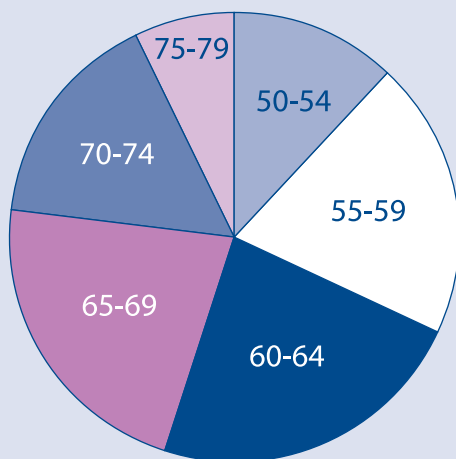
### Age

At the time of enrollment, WHI women were between the ages of 50 and 79. Today, those women are more than 15 years older. The charts below show the change in age distribution between then and now.

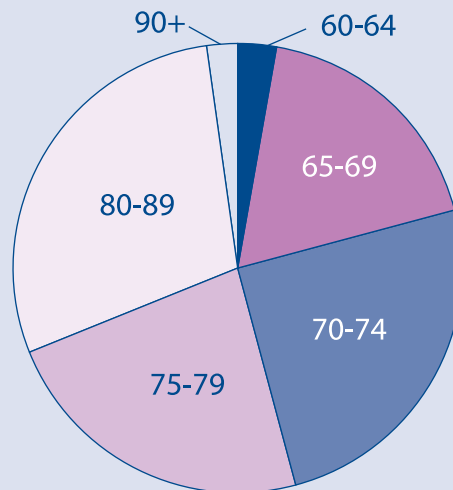
### Location

In 1993, 40 clinical centers enrolled participants from across the U.S. Where are our participants living today? WHI women are now located in all 50 of the United States, as well as 37 foreign countries, including China, India, Haiti, Nigeria, Trinidad, Israel, Finland, South Africa, Estonia, Hungary, Peru, and Japan!

AGE DISTRIBUTION AT ENROLLMENT



CURRENT AGE DISTRIBUTION





## Health and Quality of Life

As women age, it is natural that health issues begin to develop or worsen. Below are the numbers of participants who have had some of the health issues most common to women.

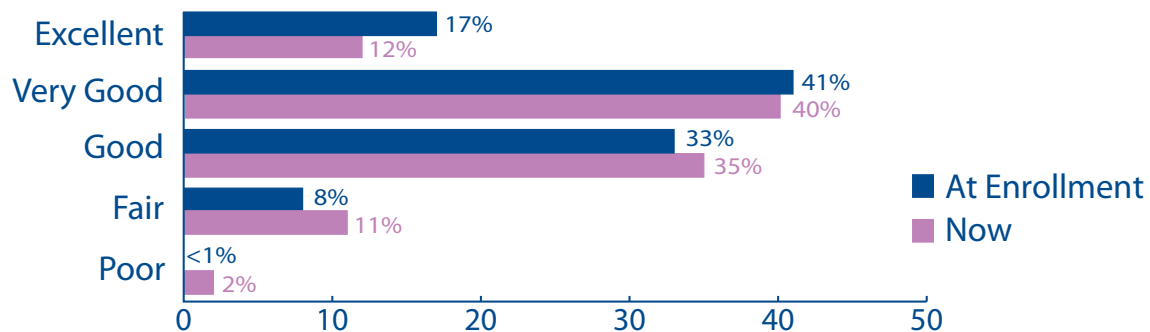


Because generally healthy women joined WHI, the rates of health issues may be lower in our participants than in the general population. Sadly, over 15,000 participants have passed away since joining the study, with cancer and heart disease reported as the main causes for death. We will be forever grateful to their contributions to women's health.

HEALTH ISSUE	HAD PRIOR TO JOINING WHI	OCCURRED SINCE JOINING WHI
High blood pressure (treated with pills)	39,652	49,756
Diabetes (treated with pills/shots)	7,167	15,011
Heart Attack	3,703	5,141
Stroke	2,165	5,097
Endometrial (uterine) cancer	2,038	1,235
Broken hip	1,404	3,233
Colorectal cancer	963	2,167
Ovarian cancer	890	802

What is the impact of aging on a woman's quality of life? Each year since the beginning of the study, we've asked women to rank their quality of life on a scale from 0 to 10, where 0 was "As bad or worse than being dead" and 10 was "Best quality of life". At the time they joined the study, women gave their quality of life an average score of **8.2**, compared with **7.8** in 2009.

And while WHI women may be aging, most still report feeling pretty well, as shown by their answer to the question: **In general, would you say your health is:**





## Activities of Daily Life

Several questions about ordinary activities of daily life were answered when women first joined the study, and again in later years, to see how abilities change with age and health changes. While some women are experiencing more limitations than they were at the time of enrollment, most women are not feeling limited at all.

DOES YOUR HEALTH LIMIT YOU IN:	NO, NOT LIMITED AT ALL	
	AT TIME OF ENROLLMENT	IN 2009
Vigorous activities, such as running or strenuous sports?	22%	15%
Moderate activities, such as vacuuming or bowling?	69%	54%
Lifting or carrying groceries?	77%	66%
Climbing several flights of stairs?	56%	42%
Walking several blocks?	80%	61%
Bathing or dressing yourself?	96%	89%

## Your Contributions to WHI

The data you have provided every year for the past 15 years help us better understand the health and daily activities of postmenopausal women. You have contributed to this knowledge by filling out questionnaires each year, and in the early years of WHI, by attending clinic visits and providing physical measures and blood samples. In the original WHI, study participants completed over 8,800,000 forms between 1993 and 2004. In the Extension Study, another 1,200,000 forms were completed between 2005 and 2010 – an amazing contribution! While it may not seem like answering one question or one form is that important, each question you answer is a piece of a larger puzzle. The more pieces you provide, the more complete the puzzle, creating a clearer and more accurate picture. We thank you for each and every form you've completed!





## Focus on Findings

**W**HI scientists continue to analyze the information you provide and report their findings in professional journals and at conferences. Over the years, hundreds of these articles have been published and many more are in progress. We encourage you to continue to visit the WHI participant website at [www.whi.org](http://www.whi.org) for updates on the latest findings. Here are summaries of a few of the many articles that were published in the past year.



### ■ **Breast Cancer after Use of Estrogen plus Progestin in Postmenopausal Women** (*New England Journal of Medicine, February 2009*)

Following the release of the findings from the Women's Health Initiative Estrogen Plus Progestin Hormone Trial (E+P), use of hormone therapy in the United States fell sharply. During that time, rates of breast cancer also went down, suggesting a relationship between stopping hormone therapy and the decrease in breast cancer. However, some researchers felt that the drop in breast cancer was too fast to be explained by lower hormone use. Others thought that the decreased rates might be due to the drop in mammography rates during the same period.

WHI investigator Rowan T. Chlebowski, M.D., Ph.D., Principal Investigator of the Torrance, CA clinical center, and other WHI scientists examined data from WHI participants to help explain the reason for the drop in breast cancer rates. In this analysis, they looked at new breast cancer rates, hormone use, and

mammography use over the same period of time in two groups of WHI women: those in the E+P Hormone Trial and those in the Observational Study.

Findings from this new analysis confirmed that the risk of breast cancer associated with estrogen plus progestin use goes down significantly once these hormones are stopped. In addition, they found that the increase in breast cancer risk seen with longer use of estrogen plus progestin is even higher than previously estimated. A woman continuing E+P hormone therapy after about 5 years doubles her annual risk of breast cancer.

The study findings suggest that the decline in breast cancer risk seen after hormone therapy was stopped was unrelated to the drop in mammography use during those same years. "These findings support the hypothesis that the recent reduction in breast cancer incidence in the United States





is predominantly related to a decrease in combined estrogen plus progestin use,” said Dr. Chlebowski.

“Postmenopausal women and their physicians should consider these findings

when weighing the risks and benefits of combined estrogen plus progestin use, especially if they plan to take the medication for more than five years” said Dr. Chlebowski.

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### ■ **Multivitamin Use and Risk of Cancer and Cardiovascular Disease in the Women's Health Initiative Cohorts** *(Archives of Internal Medicine, February 2009)*

In a study on vitamin and supplement use, Marian L. Neuhouser, Ph.D., of the Fred Hutchinson Cancer Research Center, Seattle, and other WHI colleagues analyzed data collected from all participants in the Women's Health Initiative, including those in the Hormone Trials, Dietary Study, and Observational Study. About half of Americans use dietary supplements, often because they believe that these supplements will prevent chronic diseases, such as cancer and heart disease. Scientific data supporting the benefits of supplements—including multivitamins, the most commonly used supplements—are lacking.

This lack of scientific data led Neuhouser and her colleagues to study this issue using data collected from WHI participants. A total of 41.5% of WHI participants had reported using multivitamins. Looking at WHI data, scientists did not find any significant links between multivitamin use and the likelihood of developing cancer (breast, colorectal, endometrial, renal, bladder, stomach, lung, or ovarian) or cardiovascular disease (heart attack or stroke), or of dying. In other words, postmenopausal women who take multivitamins appear to have the same risk of most common cancers, cardiovascular disease, and dying as women who do not take multivitamin supplements.

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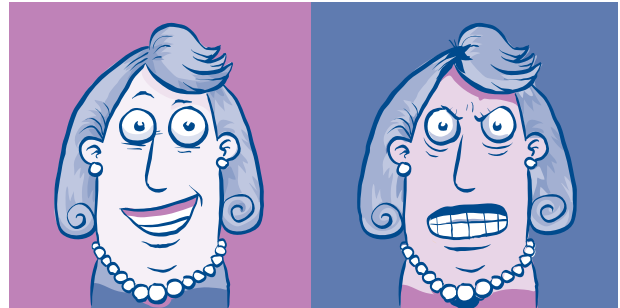




■ **Optimism, Cynical Hostility, and Coronary Heart Disease and Mortality in the Women's Health Initiative** (*Circulation, August 09*)

Dr. Hilary Tindle and other WHI investigators were interested in finding out if optimism (positive future expectations) and cynical, hostile attitudes toward others are related to coronary heart disease and mortality (death) in postmenopausal women. Using data obtained from women in the Observational Study, they found that **optimists** (women who scored at the top of the “Optimism” scale) had lower rates of heart disease and total mortality than **pessimists** (those who scored at the bottom of the scale). The most cynical, hostile women (women who scored at the top of the “Hostility” scale) also had higher rates of heart disease and death.

In terms of cancer, the most cynical, hostile women had a higher risk of cancer-related mortality and total mortality. This effect was more noticeable in black women. Black women who were optimists also had a lower risk for cancer-related death, when compared with pessimists.



**Optimism and cynical hostility are both associated with important health outcomes.**

The investigators conclusions were that optimism and cynical hostility are both associated with important health outcomes in black and white women. Future research should examine whether interventions designed to change a woman’s optimism and hostility levels can help change their health risk.

**Optimists had lower rates of heart disease, cancer-related mortality, and total mortality than pessimists.**





## ■ Risk Associated with Physical and Verbal Abuse in Women Aged 50 to 79

(*Journal of the American Geriatrics Society, October 09*)

Maggie Baker, PhD, RN, and her WHI colleagues looked at data provided by all WHI participants to study whether midlife and older women who reported physical abuse, verbal abuse, or both abuse types the previous year had higher mortality (death) risk than women who did not report abuse. Of all women, 11.3% reported physical and/or verbal abuse during the previous year. Abuse was found to predict mortality risk, regardless of the woman's age, education level, ethnicity, and health-related factors. Women who reported physical abuse had the highest risk of dying,

followed by women who reported both abuse types.

The authors overall finding was that middle-aged and older women who reported physical, verbal, or both types of

**Women who suffer physical or verbal abuse appear to have significantly higher mortality risk than women who do not.**

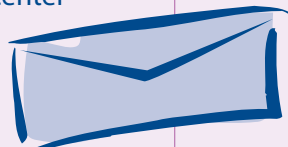
abuse the previous year had significantly higher mortality risk than women who did not report abuse. These findings highlight the need for more research into the prevention of abuse in later life.

### 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**

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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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## Stay in Touch

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

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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!



2009-10

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