Focus On Safety

Every six months, eleven experienced doctors, scientists, statisticians, nutritionists, and other medical experts from around the United States gather for an important meeting. Their purpose? To protect you and all of the women participating in the Women’s Health Initiative.

The group that meets is called the Data and Safety Monitoring Board, or DSMB. Though you may not remember it, you first read about the DSMB when you signed the initial consent form to take part in this study. The consent form states: “An independent committee of experts in medical research will be reviewing study results regularly to see if there are clear benefits or harmful side effects. You will be informed if definite benefits or harmful results are found during the study.”

The DSMB is an expert panel that was asked by WHI’s original sponsor, the National Institutes of Health, (NIH) to monitor various treatment areas of the study. This group monitors the study for the safety of its participants. None of the board members works for WHI, but they are recognized leaders in areas such as cardiology, gynecology, nutrition, behavioral science, oncology, statistics, and ethics. All NIH-funded clinical trials (studies involving people) are required to have an oversight committee like the DSMB.

Since WHI began, and until it ends, the DSMB works as a safety watchdog. While your health care provider and, to a lesser extent, your WHI Clinical Center, monitor your individual health, the DSMB looks at the safety of the study as a whole. The committee looks at study data (reports), not at individual records. Nothing the DSMB sees has a participant’s name on it, but they do see the grouped results for each part of the study. This allows them to compare the effects of the “active” study pills versus the “inactive” study pills, and to compare the Dietary Change group with the women following their usual diet.

The DSMB looks at the number and type of health events, and outcomes, participants in the study are

Continued on page 2
Focus On Safety

Continued from cover

experiencing. If they saw any harmful effects on the health of WHI participants, they would quickly respond. The board also makes sure that the Clinical Centers are encouraging women to stick with their study responsibilities—taking pills, making eating plan changes, attending clinic visits, or completing forms—so they have accurate, reliable information about the study. If the information is complete and timely, the DSMB can assure women that the different parts of WHI are safe and will provide solid information when scientists eventually study the final results.

If the study data show that some part of WHI is unsafe, the DSMB has the power to recommend stopping the study (or part of it). On the other hand, if part of WHI is shown to be very beneficial (for example, if many fewer women in the Dietary Change group developed colon cancer compared to the comparison group), the DSMB could stop the Dietary Study early and tell the public so others could make positive changes for their health, too. Also, if too many participants drop out of WHI, the DSMB could decide to stop the study for that reason; if there aren’t enough women in the study, then the results won’t be accurate.

The DSMB also follows other medical studies that are looking at some of the same things as the Women’s Health Initiative. If they see a number of studies published in scientific journals that point to something as not safe or effective for women, they recommend changes for WHI. For instance, when some other clinical trials showed that women with a uterus who took estrogen alone increased their risk of endometrial cancer, study leaders reviewed this information and recommended that all of the WHI participants in this category switch to a different hormone combination to ensure their safety.

No one yet knows what information will come from your participation in this study. But you can be assured that many medical experts are working hard so you will be safe and your efforts will lead to important answers about women’s health.

End Of Recruitment Reached

October 29, 1993, marked the enrollment of the very first woman into WHI. The very last women were enrolled on December 31, 1998. As you can see, we came very close to reaching the exact enrollment goals for the study: over 27,000 women joined the Hormone Study and over 48,000 women joined the Dietary Study. Nearly 94,000 women joined the Observational Study as well. Congratulations to each of you for helping this landmark study reach its goals! It took the commitment of every woman in WHI to achieve this. Each participant counts in making WHI a success! Recruitment for the Calcium Vitamin D part of WHI continues through the summer of 2000; you can join this part of the study at your first or second annual clinic visit. Thank you for being part of the answer!
Participant Sees Future—and Past—With WHI

Two years ago, Carol Palenshus went to an orientation session at Ohio State University in Columbus to learn more about the Women's Health Initiative. She walked away with a lot of helpful information, a determination to join the study, and a surprising encounter—Carol was reunited with a childhood friend she hadn't seen for 40 years!

Carol recalls, "Karen [Burley] was sitting a few people down from me, and about half an hour into the session, we told our names and something about ourselves. Karen asked me a couple of questions. I just didn't recognize her, but she did me. It was kind of neat. We were friends in junior high and high school."

The long-lost friends visited at length that day. They first became best friends in junior high and remained close until Karen moved away during high school to attend a school where her father taught. Lack of transportation made it difficult for the girls to keep in touch. After high school, Carol went away to college and Karen married.

Both women ended up joining WHI as part of the Dietary Study. They haven't yet been able to schedule their clinic visits so they can see each other again, but they do talk on the phone when their busy work lives allow. "We talk a lot about what we did as kids and that type of thing," says Carol. "Karen has shared a lot about her family and where they are and what they're doing, and I've told her about my brothers."

Karen drives a city transit bus in Columbus. Carol is an office manager at a busy dental practice (where her husband is a dentist). She lives in the small town of Bucyrus, about an hour and a half north of Columbus. Her distance from the Columbus Clinical Center undercuts her commitment to the study. The three-hour round-trip commute and a clinic visit often takes most of a workday and Carol works hard to juggle her work schedule to accommodate the study demands. "Sometimes it's difficult to fill out the [study] paperwork, because after being at work for 15 hours, I resent having to spend the time doing it," admits Carol. "But I do it anyhow because it's a commitment and you do things when you're committed to them."

When Carol and her husband aren't working hard building their business, they enjoy traveling. Most recently, they went to visit their daughter, who lives in Sweden. "We travel as much as we can. It's a major thing to cancel patients or to find 'babysitters' for the practice. If I had my way, some wonderful person would pay us and we would just travel all the time!" The Palenshus' plan to go to Ireland next year.

Carol views the stage she's gone through in her life as her "former lives." She traveled extensively with her husband during his military career and was an active volunteer during her children's school years. Now she has her demanding career and her participation in WHI: "I honestly feel I'm getting more out of it than I'm giving. I feel like I'm doing a good service for my body." Though she looks forward to her next "life" as a retiree, Carol's enjoying the present, too—especially when it's enriched with good friends from the past.
For Your HEALTH

■ Are you at risk for diabetes? See your doctor for testing if you have one or more of these symptoms on a regular basis: excessive thirst, frequent urination, extreme fatigue, unexplained weight loss, or blurry vision from time to time.

■ To feel your best, make sure you drink enough liquids each day. If you drink at least eight glasses of water or other liquids, you should not feel thirsty and your urine will be almost colorless. Remember that alcohol and caffeine are diuretics, which means they draw water out of your body and can cause dehydration.

■ If you have a canker sore, tea can help. For relief from these mouth sores, rub a wet, black tea bag on the inflamed area. Black tea contains tannin, which can help relieve pain and swelling. Or drink chamomile tea to soothe the sore.

■ More than 200,000 car crashes each year involve sleepy drivers, according to the National Highway Traffic Safety Administration. If you’re really tired, don’t try to wake yourself up by turning on the radio, drinking coffee, or opening your car windows. Experts say it’s best to pull over to a safe spot and take a 20-minute nap.

■ Grapefruit juice should not be taken with some prescription drugs, including calcium-channel blockers (taken for heart disease), because it can increase or decrease the effect of some medicines. It’s a safer bet to take all medications with water, unless your pharmacist specifically instructs you to take your prescription drug with milk or food.

■ Adults should get a tetanus shot at least every 10 years. But if your skin is ever broken by a rusty or dirty object, or if you are ever scratched (enough to break the skin) by an animal that lives or roams outside, you should get a tetanus shot if you haven’t had one within the last five years. Get the shot within 72 hours of being injured.

■ Here’s a trick from the National Heart, Lung, and Blood Institute to keep HDL (“good”) cholesterol and LDL (“bad”) cholesterol straight in your mind. Remember them as “H” for healthy and “L” for lethal. You want your HDL cholesterol to be as high as possible (ideally, 60 or greater) and your LDL to be as low as possible (ideally, under 130).

■ Common things can trigger headaches: poor posture, eyestrain, glare, loud noise, fumes (glue, paint, cigarette smoke, perfume, etc.), poor air circulation, hot weather, lack of sleep, sinus problems, the flu, a head cold, allergies, stress, hormonal changes, skipping meals, and eating foods you’re sensitive to. If you get a lot of headaches, look for some of these triggers in your life.

Letters
Weld love to hear feedback on the newsletter and your story ideas. We regret that we cannot answer questions about individual medical conditions. Send letters to:
WHI Matters
Fred Hutchinson Cancer Research Center
1100 Fairview Ave N, MPH-1002
Seattle, WA 98109

Staff Information
WHI Matters is produced semi-annually by the WHI Coordinating Center at the Fred Hutchinson Cancer Research Center.
Editors: Colleen Steelequist
Julie Hunt, Ph.D.
Design: Martin Brennan
Medical Hype: How to Read Between the Lines

he late Carl Sagan said, "Extraordinary claims require extraordinary proof." We would be wise to keep his words in mind as we read health news. Everyday, headlines from the world of medicine and science scream for our attention: "Drinking wine protects against heart disease," "Lower-fat diets harm older women," or "New drugs kill cancer."

These headlines—which are often contradictory—rarely tell the whole story or portray findings accurately. It is important to be able to separate fact from fiction, and breakthroughs from a new spin on old news.

A scientist may work patiently for years before coming to any conclusions about his/her particular area of research. After an experiment ends or an observation is made, the results continue to be examined by other scientists. When an article is submitted for publication in a scientific or medical journal, a group of scientists reviews the work. If the work is deemed important enough, right before it is published in a journal or read at a conference, a press release is issued and an announcement is made to the world. This often creates a media frenzy and results in the many headlines we see about health news. Such news often makes us think that the scientific process is over, but it's not. A publication is really a challenge: "Here's my result. Prove me wrong!"

Each year, thousands of clinical studies are published in medical journals—that's a lot of potential "latest studies" to hear about.

So how do you approach the latest study? First of all, it's important to take the long view on research: think of each study as one more piece of a puzzle slowly being put together. Seek answers to these questions as you read health news:

- Who funded the study? Research that's been funded by a government agency (like NIH) is less likely to be biased than a study that's sponsored by a pharmaceutical or food company with profits at stake.

- Has the study been published? Research presented at medical meetings can be cutting-edge and may grab your attention—but it's only preliminary research. Many of those studies will be rejected by major peer-reviewed medical journals because of flawed research methods or inaccurate conclusions.

- Was the study done in test tubes, animals, or humans? Some drugs that show promise in the lab or in animals don't affect humans the same way. Studies carried out on people (clinical trials) have the most impact. Also note if the study included both men and women. For instance, the French study of wine protecting against heart disease included only men. Other studies have presented strong evidence that the risk of breast cancer rises in women who drink alcohol regularly.

- How big was the study? Does the article tell you how many people were studied and how long they were followed? In most cases, the bigger the study group, and the longer the follow-up, the more important the findings. Unfortunately, a lot of what you hear in news reports is based on results from a handful of people studied. For example, the study that sparked the headline, "Low-Fat Diets Harm Older Women," included only 10 women and lasted just three weeks.
What kind of study was it? The type of study conducted is critical information, but is often overlooked in a short article or 30-second sound bite. No study is without flaws, but the gold standard for showing cause and effect is the double-blind, controlled clinical trial, in which people are assigned by chance to a control (placebo) group or an experimental (the real thing) group. Neither the researchers nor the participants know who's getting what until the study ends. This type of study design allows scientists to compare groups that are alike in all ways—except that some got treated and some didn't—so they can tell if a drug or treatment actually helped.

In other kinds of studies, however, researchers use information from medical records and rely on people's memory of past events to reach a conclusion about the present. For example, in trying to find what causes a certain type of cancer, researchers sometimes compare cancer patients with cancer-free people of similar age, sex, and lifestyle in order to figure out how the sick people are different from the healthy people; this is called a case-control study. Scientists can also form a group of study participants, ask them about their lifestyle, diet, etc., and then follow the group for years, keeping track of who becomes ill. Next, the scientists try to figure out what the people who became sick had in common (a cohort study). Unfortunately, these studies have a lot of room for error, especially in how well participants remember past events.

What do the words really mean? "Associated with" or "linked to" doesn't mean "is caused by." In a study, "significant" means statistically significant; that is, a link between two things (cause and effect) is not likely to be due to chance. "Risk" is another grab-your-attention word that can be scary, but misleading. Something that "doubles your risk" is worth noting, but your risk may only have changed from one in a million to two in a million—still a very small risk.

How should I respond? If the study you're reading about was published in a reputable journal and you're satisfied that the research was solid, keep asking questions. Do the findings really apply to you? Are you the same age and sex as the participants? Do you have the same health history as the study subjects? All studies have their weaknesses. If possible, visit your local library and read the entire study. The authors usually come right out and list the limitations of their study. If it still seems to apply to you, bring the article along the next time you see your health care practitioner. He/she may be able to shed some light on the research and whether or not it applies to your health. Your WHI clinic practitioner might be able to answer some of your questions about the latest research on women's health.

Above all, remember that medicine and research advance slowly. One study on its own rarely changes accepted theory or recommendations. Look beyond the headlines and seek out the science that deserves your attention.
Stay In Touch

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

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

Arizona Prevention Center
Phoenix, Arizona • (602) 241-9216

Tucson, Arizona • (520) 321-7440

Baylor Clinical Center
Houston, Texas • (713) 793-8366

Berman Center for Clinical Research
Minneapolis, Minnesota • (612) 343-7900

Brigham and Women's Hospital
Charlestown, Boston • (617) 278-0782

Center for Health Research
Portland, Oregon • (503) 355-6759

Chariton Memorial Hospital
Fall River, Massachusetts • (800) 742-9446

Denver Clinical Center
Denver, Colorado • (303) 966-8000

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

Evansville Hospital
Evansville, Indiana • (812) 470-1136

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

The George Washington University
Washington, DC • (202) 875-2270

Kaiser Permanente—Bay Area Clinic
Oakland, California • (510) 450-2275

Medical College of Wisconsin
Milwaukee, Wisconsin • (414) 257-5152

Memorial Hospital of Rhode Island
Providence, Rhode Island • (401) 722-3446

Nevada Clinical Center
Reno, Nevada • (775) 784-4906

New Jersey Medical School
Newark, New Jersey • (973) 972-6107

New Brunswick, New Jersey • (732) 235-0546

Northwestern University
Chicago, Illinois • (312) 928-7887

Ohio State University
Columbus, Ohio • (800) 251-1175

Chicago, Illinois • (312) 942-5395

Stanford Women's Health Initiative
Stanford, California • (650) 725-9099

Stony Brook Clinical Center
Stony Brook, New York • (516) 444-8280

South Bay WHI Program
Torrance, California • (310) 222-8010

UAB Preventive Medicine
Birmingham, Alabama • (205) 794-6873

UCLA Women's Health Initiative
Los Angeles, California • (800) 359-8252

UMASS/FALLON Clinical Site
Worcester, Massachusetts • (508) 793-8000

University of California, Davis
Sacramento, California • (916) 734-3219

University of California, Irvine
Orange, California • (714) 456-7241

University of California, San Diego
Chula Vista, California • (619) 452-6980

La Jolla, California • (858) 696-7570

University of Cincinnati
Cincinnati, Ohio • (513) 584-0616

University of Florida
Gainesville, Florida • (800) 444-4594

Jacksonville, Florida • (904) 856-5075

University of Iowa
Iowa City, Iowa • (800) 341-5355

Dee Moline, Iowa • (319) 342-8164

Iowa City, Iowa • (319) 814-9535

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

University of North Carolina
Chapel Hill, North Carolina • (919) 568-5628

University of Pittsburgh
Pittsburgh, Pennsylvania • (412) 624-3337

University of Wisconsin
Madison, Wisconsin • (608) 263-3237

UTHSC
San Antonio, Texas • (210) 567-1850

UT Prevention Center
Memphis, Tennessee • (901) 767-9700

University at Buffalo
Buffalo, New York • (716) 829-3138

Women's Health Hawaii
Hollywood, Hawaii • (808) 547-9814

WHI of the Triad
Greensboro, North Carolina • (336) 272-0453

Winny-Salem, North Carolina • (336) 777-3245

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

If you have questions, use the telephone number above to contact your local Clinical Center.

Calling 1-800-54-WOMEN will no longer connect you with your local center.

Women's Health Initiative
Medical College of Wisconsin
PO Box 26569
Milwaukee, WI 53226

Change Service Requested

RUSH RATE U.S. POSTAGE
PMD
SEATTLE, WA
PERMIT NO. 3147