



Q&A

Questions and Answers about the Women's Health Study

Q. Recent news reports about the Women's Health Study (WHS), published in the *Journal of the American Medical Association (JAMA)*, suggest that vitamin E provides no benefit for the prevention of cancer or cardiovascular disease, but your information seems to suggest otherwise. Why the conflict?

A. In reporting on the study, the publication focused on the **primary** conclusions from the research—which showed no significant reduction in the risk of cardiovascular disease overall—and minimized the importance of the unexpected **secondary** findings. These secondary findings indicated a 24 percent reduction in cardiovascular deaths among women who took vitamin E as part of the 10-year trial. Additionally, the secondary findings showed that for women 65 and older, there was a 49 percent reduction in cardiovascular deaths. The study's authors stated that these outcomes "...differ from the totality of evidence and should be explored further." Other scientists, including those at CRN, believe the secondary conclusions are encouraging news for vitamin E. In addition, there were no benefits shown from this study with regard to vitamin E and cancer. However, other studies do suggest that vitamin E may reduce the risk of certain cancers.

Q. What do you mean by primary versus secondary findings in a study?

A. In planning a study, researchers identify the main outcomes or measurements of interest. This is often based on what has been observed in previous studies. In the case of vitamin E, research suggested that supplementation with the nutrient may decrease the risk of certain cancers and cardiovascular disease (including cardiovascular events, such as strokes, heart attacks, etc.). Thus the WHS researchers defined these as the "primary" outcomes or endpoints. During the course of or following the completion of a study, researchers often encounter unexpected outcomes, or outcomes that tend to follow those of primary interest, such as death from disease, rather than the initial diagnosis of disease itself. These are often termed "secondary" findings or endpoints. In the case of WHS, a reduction in cardiovascular death in the group of women supplemented with vitamin E was such a finding. A "primary" or "secondary" label does not necessarily speak to the importance of a finding, but rather whether or not it was defined at the outset as an outcome to be measured.

Q. Is the Women's Health Study good news?

A. We think so. The study found some unexpected benefits for women who took vitamin E supplements over the course of the 10-year trial, most notably a reduction in cardiovascular deaths, particularly among women 65 and older. While this was not the primary finding of the research, CRN still believes it to be significant. The study's authors acknowledged this positive outcome and said it deserved further research, but they are not recommending vitamin E to prevent cardiovascular disease. CRN believes that even though these findings were unexpected, they are still positive news.

More questions and answers about the Women's Health Study

Q. Can vitamin E really help prevent cardiovascular disease in women?

A. There is no magic bullet to prevent cardiovascular disease. Research indicates that healthy lifestyle choices, like proper diet, regular check-ups and routine exercise, all help prevent chronic disease. Dietary supplements, such as vitamin E, provide the best benefit when they are incorporated into an overall healthy lifestyle.

Q. Because the WHS found no benefit for cancer, should I stop taking vitamin E?

A. No. As an essential nutrient, vitamin E promotes good health overall, and studies show that most people don't get enough vitamin E from diet alone. If consumers focus only on the results of this one study with respect to just cancer, they will potentially miss out on the other positive benefits that vitamin E provides. Particularly given that the study found no harm, our advice is that consumers should continue taking a vitamin E supplement as protective insurance for health.

Q. What did the WSH find in terms of safety?

A. That's another piece of good news. The WHS is the largest and longest clinical trial to date on vitamin E, having studied 20,000 women taking vitamin E over a 10-year period. The WHS found that 600 IU of vitamin E supplements every other day did not increase total mortality in healthy women. This is in contrast to the over-generalized headlines seen in the past six months that suggested otherwise. At the heart of these misleading stories was a controversial meta-analysis that inappropriately drew conclusions for the whole population based on a combination of studies of people who were already at grave risk with existing life-threatening diseases. In fact, in the WHS, there were no differences between reported adverse effects for the women who took vitamin E versus those who took a placebo, apart from a small, but statistically significant, increase in the risk of nose bleed. CRN believes the WHS results reaffirm vitamin E's safety.