

Setting the Record Straight on Vitamin E

A recently published report in the online edition of the *Annals of Internal Medicine* (Nov. 10) alleges that high doses of Vitamin E may increase the risk for mortality, and the report has been widely disseminated this week by the media. The Council for Responsible Nutrition and other scientific experts disagree with the conclusions of the study which is the basis for this report. In addition, the National Institutes of Health and the Institute of Medicine, which sets the recommended daily allowance for vitamins in the United States, both state that Vitamin E is safe.

Why the Study Is Flawed

There are significant flaws and inaccuracies in this meta-analysis conducted by researchers from Johns Hopkins University. A meta-analysis is not a new study. It is simply a compilation of previously run large-scale clinical studies. Scientific experts have noted major problems with the authors' conclusions drawn from this meta-analysis, which ignored the vast majority of existing published studies, for the following reasons:

- There was a bias in the selection of the studies to review. The researchers selected only 19 of the 2,170 studies available on Vitamin E.
- Eighteen of the 19 studies reviewed did not support the researchers' conclusions. The only study that did support their conclusions was a hormone replacement therapy study that examined the effects of using Vitamin E and estrogen in combination, which confuses the results of this study.
- Less than half of the studies reviewed were done on Vitamin E alone.
- Additionally, studies using higher than 400 IU were done on diseased populations, whereas studies using less than 400 IU were done on healthy people.
- While the authors concluded that Vitamin E supplementation did not affect all-cause mortality (death risk), with no supporting data they recommended that people should not exceed a daily dose of 400 IU.
- The National Institutes of Health (NIH) and the Institute of Medicine, which sets recommended daily dietary guidelines for vitamin supplements, have identified the tolerable upper level of natural Vitamin E intake at 1500 IU/day for adults. The Institute of Medicine defines the upper limit as "the maximum intake of a nutrient that is likely to pose no risk of adverse health effects in almost all healthy individuals in the general population."

Dr. Jeffrey Blumberg, Associate Director of Tufts University's Human Nutrition Research Center on Aging, member of Shaklee's Scientific Advisory Board, and widely recognized nutrition expert, emphasized that the research used in the study looked at people already at high risk of death, which can't be used to determine what's good for healthy people.

Dr. Blumberg also stated that "these investigators selected 19 specific studies to analyze. In doing so, they also selected not to employ a vast number of studies that show no harm from Vitamin E and a great deal of benefit."

In reaching their conclusions, the authors ignored a huge body of research that supports the health benefits of Vitamin E supplementation.

Vitamin E Is Safe and Effective

There are more than 1,000 studies that support the safe and efficacious use of Vitamin E supplements, including several studies that were reviewed in this recent analysis. Research studies on Vitamin E supplements have linked the antioxidant to numerous health benefits including reduced progression of advanced age-related macular degeneration, reduced occurrence of cataracts, slowing the progression of Alzheimer's Disease, slower progression of atherosclerosis, lower incidence of non-fatal myocardial infarction, and reduced incidence of upper respiratory infection, to name just a few.

For instance:

- 1993 – Supplementation with Vitamin E was associated with a 30-40% reduced risk for coronary disease in a study of 90,000 nurses (Nurses Health Study; *NEJM* 328:1444-1449).
- 1993 – Total Vitamin E intake was inversely related to the risk of colon cancer; those with a highest Vitamin E intake had the lowest incidence of colon cancer (Iowa Women's Health Study; *Cancer Res*:53:4230-4237).
- 1994 – Levels of Vitamin E intake were inversely correlated with coronary deaths in both women and men in a large (>5000 people), long-term (14 year follow-up) Finnish study (*Am. J. Epidemiol.* 139:1180-1189).
- 1997 – A review of the literature concerning vitamin E and breast cancer concluded "although epidemiologic study results have been inconsistent, further study of this **nontoxic** vitamin is warranted." (*Nutr. Cancer* 27:109-117).
- 2000 - Supplementation with Vitamin E may prevent ischemic stroke in high risk hypertensive patients (*Arch. Neurol.* 57:1503-1509; analysis of data from the Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study).
- 2004 – Protective effect of Vitamin E supplementation on upper respiratory tract infections in elderly nursing home residents (*JAMA* 292:828-836).

- 2004 – Supplementation with Vitamins E and C in combination is associated with reduced prevalence and incidence of Alzheimer's Disease (Arch. Neurol. 61:82-88; this study is from Johns Hopkins).
- FDA – Allows qualified health claim regarding “consumption of antioxidants (including Vitamin E) and reduced risk of some forms of cancer.”

This week's headlines aside, the preponderance of scientific and clinical data shows well-established benefits of Vitamin E for otherwise healthy individuals. Supplementation with vitamins, including Vitamin E, makes sense in support of a healthy lifestyle, and for people who desire nutritional insurance for the gaps left unfilled by the typical diet.

What Should You Do?

We want to reassure you that you do not need to change your vitamin regimen. Use supplements “as directed” on the label. As always, continue to look to Shaklee to provide the best and most reliable information on health and wellness.

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FOR IMMEDIATE RELEASE Contact: Judy Blatman at 202-204-7962

**COUNCIL FOR RESPONSIBLE NUTRITION (CRN) QUESTIONS CONCLUSIONS
REACHED BY RESEARCHERS
IN RECENT VITAMIN E META-ANALYSIS**

Washington, D.C., *November 10, 2004* – A meta-analysis on vitamin E and all-cause mortality (ACM) from today's on-line issue of *Annals of Internal Medicine* inappropriately tries to draw conclusions for the whole population based on a combination of studies of people who were already at grave risk with existing diseases including cancer, heart disease, Alzheimer's, Parkinson's and kidney failure, says the Council for Responsible Nutrition (CRN).

The researchers themselves noted limitations in their meta-analysis, stating “the generalizability of the findings to healthy adults is uncertain. Precise estimation of the threshold at which risk increases is difficult.” Yet they go on to make sweeping generalizations about the use of vitamin E and all-cause mortality for the whole population, although they provide no evidence that these kinds of effects would occur in healthy populations.

“This is an unfortunate misdirection of science in an attempt to make something out of nothing for the sake of headlines,” comments John Hathcock, Ph.D., vice president, scientific and international affairs, CRN. The meta-analysis combined 19 individual studies, eighteen of which showed no statistically significant increase in mortality, squeezing out an overall finding of risk. Combining numerous clinical trials into a single large cohort gave greater statistical power but failed to capture the limitations of each study included.

Most of the trials involved middle-aged to elderly persons who had heart disease or other serious conditions or were at risk of disease. The placebo groups had an ACM rate of 1022/10,000 and the high-dose (defined by the researchers as 400 IU and up) vitamin E subjects had an ACM increase of 39/10,000. Says Dr. Hathcock, “The overall conclusion of this meta-analysis is driven by the results from a few of these clinical trials, some of which are suspect and/or dated. For example, the WAVE trial (Waters et al., 2002) made no correction for multiple comparisons, and found one of 22 comparisons ‘significant.’ This is 1/22 whereas 1/20 would have been expected on a random basis. In other words, they found nothing.”

Dr. Hathcock added, “In reviewing the totality of evidence on vitamin E, including all clinical trial data and several large observational studies, CRN agrees with the Institute of Medicine in finding vitamin E supplements safe at levels of at least up to 1,000 mg (1,600 IU) for normal, healthy adults. This meta-analysis provides no convincing evidence to the contrary.”

Note to Editor: The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing dietary supplement industry ingredient suppliers and manufacturers. CRN members adhere to a strong code of ethics, comply with dosage limits and manufacture dietary supplements to high quality standards under good manufacturing practices. For more information on CRN, visit <http://www.crnusa.org>.