



## FACT SHEET

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### Vitamin E Meta-Analysis: What Consumers Need to Know

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#### Background

Researchers at Johns Hopkins University recently released data from a meta-analysis of 19 studies conducted on patient groups taking vitamin E. The researchers have interpreted their results to suggest that high doses of vitamin E may be associated with a slightly increased risk of mortality.

The ensuing publicity and resulting media stories have been highly alarmist in nature, unduly causing widespread confusion and safety concern among consumers currently taking supplements that contain vitamin E.

#### What consumers should know and do

- There are a great number of problems with the Johns Hopkins study and the way it has been reported in the media.
- The vast body of scientific evidence supports the continued safe use of supplements containing vitamin E.
- Vitamin E has been associated with a number of health benefits, including reduced risk of heart disease, reduced risk of age-related macular degeneration, delayed progression of Alzheimer's disease, and reduced rates of several types of cancer, including prostate cancer.
- Consumers who already are using vitamin E should continue to use it with confidence.

#### Issues

The major issue is three-fold:

- The study's results are being misinterpreted and misrepresented.
- The larger body of science is being ignored.
- Consumers aren't getting the solid advice they need.

#### Problems with the study and its reporting

- The meta-analysis found no increase of all-cause mortality risk, overall—Of the 19 clinical trials analyzed for the meta-analysis, 18 found no statistically significant increase in total mortality for those using vitamin E. When combining all 19 clinical trials, the study found no significant increase in total mortality. In authors' own words, "Overall, vitamin E supplementation did not affect all-cause mortality."
- The meta-analysis sample was not representative of the population—The meta-analysis looked at studies that included many patient groups who already had increased risk factors for mortality, such as Alzheimer's disease, Parkinson's disease, kidney failure, or heart disease.
- The meta-analysis findings may not apply to healthy adults—While the study did find that low doses of vitamin E slightly decreased total mortality and high doses (400 IU or more) of vitamin E slightly increased total mortality, it is questionable whether this finding has any practical meaning. Most of the high-dose studies sampled populations already having various diseases, leading the authors to note "generalizability of the findings to healthy adults is uncertain."
- The meta-analysis used questionable methodology for identifying high doses—The researchers' decision to select 400 IU as the cutoff between the low-dose and high-dose groups is arbitrary and lacks a clear scientific basis. Two studies used 330 IU – which is not significantly lower than the 400 IU cutoff and therefore very easily could have been included in the high-dose group. Had the researchers done so, the results may have been different.

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### More facts on the vitamin E meta-analysis

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- Reports on the meta-analysis have ignored the sample studies' intentions—The fact that the studies sampled were conducted for other reasons and differ greatly from each other has been overlooked. For example, the studies were originally published over the course of a decade all over the world. Also, vitamin E was given in the studies for a variety of reasons, including reducing the risk of heart disease, cancer, and macular degeneration, as well as delaying the progression of cataracts, kidney disease, and Alzheimer's and Parkinson's diseases at doses ranging from 16.5 to 2000 IUs.
- Reports on the meta-analysis have ignored the sample studies' other findings—In focusing on the shaky suggestion of increased mortality, the researchers and news media have omitted the fact that several of the studies sampled actually found vitamin E to be beneficial.
  - One study in England showed that vitamin E at levels of 400 and 800 IU reduced the risk of heart attack by 75% in men who already had symptoms of heart disease.
  - A study in patients with kidney failure found a reduced risk of heart attacks and of death from heart disease in people who were given 800 IU of vitamin E.
  - A study found that vitamin E at levels of 400 IU reduced the risk of age-related macular degeneration, when administered in combination with other nutrients.

### What the science really says

- Vitamin E has been found to be safe—The Institute of Medicine, a scientific advisory body, has concluded that vitamin E is safe for chronic use in the general population at levels up to 1000 mg (1000 IU synthetic vitamin E, 1500 IU natural vitamin E).
- Vitamin E has been found to be beneficial—The larger body of epidemiological studies has shown benefits from vitamin E.
  - A Harvard study of more than 80,000 nurses found a 41% reduction in the risk of heart disease in nurses who had used vitamin E supplements for at least two years.
  - A study of almost 40,000 male health professionals found that men who took vitamin E supplements for more than two years experienced a 37% reduced risk of heart disease.
  - A National Institute of Aging study in 11,000 elderly persons found that those who used supplements of vitamins C and E had a 53% reduction in mortality from heart disease and a 42% reduction in all-cause mortality, compared to non-users.
- Consumers do not get enough vitamin E from diet alone—The Recommended Dietary Allowance of vitamin E is 15 mg, and most people do not achieve that level from diet alone. Supplements and multi-vitamins help fill that gap.
- More studies are under way—A number of new clinical trials are being conducted to reconfirm the safety and efficacy of high-dose vitamin E. In the wake of recent media alarmism, researchers are working to reassure participants that vitamin E is safe, and that the research should continue. Research includes:
  - The Women's Health Study, involving over 40,000 female health professionals;
  - The Physicians' Health Study, involving thousands of U.S. doctors;
  - The Women's Antioxidant Cardiovascular Disease Study; and
  - The National Cancer Institute's Selenium and Vitamin E Chemoprevention Trial (SELECT), which is evaluating the effects of these two nutrients in protecting against prostate cancer in more than 30,000 men.