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Review of Prostate Cancer Prevention Study Shows No Benefit for Use of Selenium and Vitamin E Supplements

Initial, independent review of study data from the Selenium and Vitamin E Cancer Prevention Trial (SELECT), funded by the National Cancer Institute (NCI) and other institutes that comprise the National Institutes of Health shows that selenium and vitamin E supplements, taken either alone or together, did not prevent prostate cancer. The data also showed two concerning trends: a small but not statistically significant increase in the number of prostate cancer cases among the over 35,000 men age 50 and older in the trial taking only vitamin E and a small, but not statistically significant increase in the number of cases of adult onset diabetes in men taking only selenium. Because this is an early analysis of the data from the study, neither of these findings proves an increased risk from the supplements and both may be due to chance.

The Southwest Oncology Group (SWOG), an international network of research institutions, coordinates SELECT at more than 400 clinical sites in the United States, Puerto Rico, and Canada.

SELECT participants are receiving letters explaining the study review and telling them to stop taking their study supplements. Participants will continue to have their health monitored by study staff, which may include regular digital rectal exams and PSA (prostate-specific antigen) tests to detect prostate cancer. Investigators intend to follow the participants for about three years to determine the long-term effects of having taken either supplement or placebo and to complete a biorepository of blood samples that will be used in extensive molecular analyses to

give researchers a better understanding of prostate cancer, other cancers, and other diseases of male aging. This additional data collection is a vital part of the study.

Neither the men nor their physicians know which supplements or placebos the men have been taking, a procedure known as blinding or masking. As followup of the SELECT participants continues, the participants will continue to be blinded. A blinded followup may avoid unintentional bias and potentially false conclusions. However, at the request of a participant, they will be informed which supplement, if any, they received.

"SELECT was always designed as a study that would answer more than a single question about prostate cancer," said Eric Klein, M.D., a study co-chair for SELECT, and a physician at the Cleveland Clinic. "As we continue to monitor the health of these 35,000 men, this information may help us understand why two nutrients that showed strong initial evidence to be able to prevent prostate cancer did not do so."

SELECT was undertaken to substantiate earlier, separate findings from studies in which prostate cancer was not the primary outcome: a 1998 study of 29,133 male smokers in Finland who took vitamin E to prevent lung cancer surprisingly showed 32 percent fewer prostate cancers in men who took the supplement, and a 1996 study of 1,312 men and women with skin cancer who took selenium for prevention of the disease showed that men who took the supplement had 52 percent fewer prostate cancers than men who did not take the supplement.

Based on these and other earlier findings, in 2001, men were recruited to participate in SELECT. They were randomly assigned to take one of four sets of supplements or placebos, with more than 8,000 men in each group. One group took both selenium and vitamin E; one took selenium and a vitamin E placebo; one took vitamin E and a selenium placebo; and the final group received placebos of both supplements.

It should be noted that in 2003, while SELECT was recruiting men, a different SWOG-sponsored study reported that the drug finasteride reduced the incidence of prostate cancer by 25 percent. When this was discovered, men on SELECT were informed and allowed to take finasteride. Finasteride has not yet been approved by the U.S. Food and Drug Administration for prostate cancer prevention.

Except for skin cancer, prostate cancer is the most common type of cancer in men in the United States. In 2008, there will be an estimated 186,320 new cases of prostate cancer and 28,660 deaths from this disease in the United States. "Finding methods to prevent and treat

prostate cancer remains a priority for the NCI, and with the aid of new molecular diagnostic tools and applications, we hope to continue to make headway in reducing deaths and new cases of this disease," said NCI director John E. Niederhuber, M.D. "The science of cancer prevention is also leading toward individualized, molecular prevention, in which we will calculate risk and design preventive steps based on an individual's genome."

SELECT has been funded by NCI for $114 million, with additional monies from the National Center for Complementary and Alternative Medicine, and with substudies funded and conducted by the National Heart, Lung and Blood Institute, the National Institute of Aging and the National Eye Institute at NIH. The substudies were evaluating the effects of selenium and vitamin E on chronic obstructive pulmonary disease, the development of Alzheimer's disease, and the development of macular degeneration and cataracts, and will continue without participants taking study supplements. An NCI-funded substudy is looking at the effects of the supplements on men who developed colon polyps.

"The SELECT trial owes a tremendous debt to our volunteers, the thousands of men who offered their time and enthusiastic participation, all in the interest of a future when prostate cancer can be prevented," said Laurence H. Baker, D.O., chairman of the Southwest Oncology Group. SELECT investigators are analyzing the data and will submit the analysis for publication in a peer-reviewed medical journal.

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For a Q&A on SELECT, please go to
http://www.cancer.gov/newscenter/pressreleases/SELECTQandA.

The Southwest Oncology Group (http://swog.org) is one of the largest cancer clinical trials cooperative groups in the United States. Funded by research grants from the National Cancer Institute, part of the National Institutes of Health, the group conducts clinical trials to prevent and treat cancer in adults, and to improve the quality of life for cancer survivors. The group's network of more than 5,000 physician-researchers practice at nearly 550 institutions, including 18 NCI-designated cancer centers. Headquartered in Ann Arbor, Mich. (734-998-7130), the group has an operations office in San Antonio, Tex., and a statistical center in Seattle, Wash.

NCI leads the National Cancer Program and the NIH effort to dramatically reduce the burden of cancer and improve the lives of cancer patients and their families, through research into prevention and cancer biology, the development of new interventions, and the training and mentoring of new researchers. For more information about cancer, please visit the NCI Web site at http://cancer.gov or call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).