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The Newsletter For SELECT Men

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My First Reaction To The News

by Nick Mazzarella, SELECT Participant and NPAB Chairman

On Monday, October 13, I received an email from the SELECT Statistical Center advising me that there would be a conference call with the other members of the NPAB to review and discuss some very important information about the SELECT study. Attached to that email was a draft of a letter that would eventually be sent to all SELECT participants with detailed information. My fellow NPAB members and I, along with a handful of people from the SELECT staff, were the first to receive this news directly from the study leadership. By now, you also have received news of these changes.

I had to read the letter three times before it started to sink in. "Could this be?" I thought. Could the SELECT study, which has been going on for more than five years, be over with no more fanfare than a letter? This, after all the time and effort that was put into the study by thousands of participants and staff members throughout North America? I was surprised, disappointed, and very confused. I thought, "This can't be, it can't just end this way."

We had our conference call and were given more details. The ten members of the NPAB were asked to make suggestions and revisions to the draft letter. Rather than becoming depressed and dejected, we rolled up our

sleeves and got to work doing exactly what our group was created to do and what our mission statement mandates that we do. That is, to advise SELECT through review and suggested revision of procedures and materials that promote participant adherence and ensure the satisfactory completion of this important clinical trial.

Suddenly, it dawned on me – *SELECT isn't over!* We've merely moved into another phase, a phase that's just as important as the one we've been in for over five years. But now, SELECT is just a little different. There's still much to learn, lots of conclusions left to come to and for science to develop.

We were glad to be able to contribute to the letter that you received. We hope it relieved any apprehension you may have had, and that it helps to keep you energized and motivated to complete the SELECT trial.

As the incoming 2009 Chairman of the NPAB, I take great pride in our joint contribution to SELECT. I look forward to continuing with you as we carry out our mission, particularly as events have moved us forward into a new and different direction. It may not be the direction we all anticipated, but we will move forward nonetheless.

SELECT Participants -- True Heroes

by Ulyses Wright, SELECT Participant and NPAB Past Chairman

The first SELECT participant was randomized in August 2001 and more than 35,000 others joined him in the SELECT study. All of us wanted to participate in the SELECT study for various reasons, but with a common goal to see if prostate cancer can be prevented. We were asked to take two study supplements daily, and to visit our local SELECT site every six months to pick up new bottles of supplements and to discuss our progress on the study. Well, for some, that has proven to be easier said than done. A few SELECT sites have had to close, and their participants have been asked to travel farther to visit a SELECT site. The unfortunate event of hurricane Katrina, as well as other natural disasters, has displaced many SELECT participants. But, through it all our SELECT participants continue to go forward.

As past Chairman of the NPAB, I had the opportunity to meet with many of the SELECT participants and their significant others. It was such a joy to meet these folks face-to-face, and to hear their stories about why they joined the SELECT study. The men who joined SELECT are volunteers who agreed to participate in what we feel is a worthwhile endeavor. We were all asked to make a long-term commitment to being in the study. Most of us continue to honor our commitment to SELECT. I am very proud of the SELECT participants. As I look toward the end of the study, I can see that the true heroes of SELECT are the participants -- those men throughout the United States, Puerto Rico, and Canada who stepped up and continue to partner in this medical research.

Thank you all for being part of this important effort and for being *true heroes!*

Selenium and Vitamin E Cancer Prevention Trial (SELECT)

SELECT -- An Overview

Where are we today? What does tomorrow hold?

As you are aware, the SELECT Data and Safety Monitoring Committee (DSMC) met in September 2008 to review the data that has been collected to date. We thank all of you who volunteered to take part in this important research. Because of your dedicated efforts in following the guidelines regarding taking your Study Supplements, there was enough information available for the DSMC Committee to make a decision about the effectiveness of the Study Supplements. These data showed that vitamin E and selenium, taken alone or together for an average of five years, did not prevent prostate cancer. These data also suggest, but do not prove, that vitamin E may slightly increase the chance of getting prostate cancer, and that selenium may increase the chance of getting diabetes mellitus. Investigators from the Study leadership and the National Cancer Institute (NCI) carefully reviewed the information and agreed that participants in SELECT should stop taking their Study Supplements.

As soon as was possible, a letter announcing the news was prepared and sent to every participant. The letter also instructed all participants to stop taking the Study Supplements, but to keep the bottles and any remaining Study Supplements. These are to be taken to your Study Center at your next scheduled visit. You may continue to take the Study Multivitamin provided by SELECT.

It is important that you know that the SELECT research study is not over! We now know that selenium and vitamin E do not prevent prostate cancer. While this may not be what you had hoped to learn, it does underscore the

importance of scientific clinical trials. The health benefits of both selenium and vitamin E have been studied in many clinical trials targeting various diseases over many years. The results of those trials were inconclusive, but, at the same time, they begged further investigation. Thanks to you we finally have an answer. This is an important public health finding that affects future research projects, as well every individual who takes supplements. Prostate cancer prevention researchers may now focus their research efforts, and dollars, away from selenium and vitamin E.

Even though you are no longer taking your Study Supplements, you will continue your regular schedule of appointments with your Study Center. We will learn more about the effects of the Study Supplements as we continue to monitor your health. As one of the largest medical studies of men, SELECT will help answer many critical questions about men's health. This knowledge will assist scientists in the future.

If you want to know now what Study Supplements you were taking, get in touch with your Study Site and they will make sure you receive this information. ***At the end of the study, all participants will be told what they were taking.*** If you are concerned about your risks concerning vitamin E and prostate cancer, or selenium and diabetes, the safest course of action is to presume that you were taking vitamin E and selenium. Discuss this with your doctor. Based on your individual health history, additional testing may be recommended. If that is the case, be sure to notify your Study Center.

SELECT...Different, But Still the Same

This "Special Edition" newsletter focuses on the recent news about SELECT and the changes that have been made in the study. We've recapped the changes to SELECT and their impact on you and on future research. Now, it's time to complete the picture and review what remains the same in SELECT:

- **You are still a valued participant at your SELECT Study Site.** This means you will continue to visit your study site and provide health and medical information to the study staff. Blood pressure checks, weight records, and your responses to questions asked provide an ongoing snapshot of your overall health. These can reveal health issues that need attention before they become serious conditions. Sometimes these study site visits even prove beneficial to someone other than yourself. Earlier this year, SELECT participant Bill Elliott met with Amanda Kraehmer, RN, Prevention Coordinator, for his scheduled visit at Thomp-

son Cancer Survival Center in Knoxville, Tennessee. Based on guidelines for his age, Ms. Kraehmer advised him to make an appointment for a colorectal screening. This was something Elliott had put off over the years, but after discussing it with his family physician, he made an appointment to have the procedure done. After discussing it with him, Elliott's wife followed his example and made an appointment for the screening. While Elliott received a clean bill of health, his wife did not. She was found to have low-grade colon cancer. The good news is, it was found early and successfully treated with radiation and chemotherapy. Says Elliott, "My wife had no symptoms. Were it not for Amanda's strong recommendation that I get a colorectal screening, we wouldn't have made the appointments. She saved my wife's life. I want to tell everyone -- don't put it off, make that appointment now! It could save YOUR life!"

SELECT...Different, But Still the Same (Continued)

- As a participant of SELECT you and one other family member are eligible to receive the SELECT multivitamins. These multivitamins do not contain selenium or vitamin E. There is no cost to you for these multivitamins.

- There are four additional studies associated with SELECT. PREADVISE focuses on Alzheimer’s disease; RAS targets Chronic Obstructive Pulmonary Disease (COPD); colorectal adenomas and colorectal cancers are being studied in the ACP (adenomatous colorectal polyps) Study; and SEE addresses two diseases of the eye, Age-Related Macular Degeneration (AMD) and cataract. The status of these studies has not changed. If you are enrolled in any of them, you will continue to follow their guidelines. Enrollment is still open for the PREADVISE, SEE, and ACP studies.

- Participants receive the CHOICE newsletter two times a year. This is your forum and you have the opportunity to submit questions, comments, and suggestions.

- Your participation in SELECT provides a wealth of valuable information that will be used well into the future. Its impact will change lives. Right now, you can proudly declare, “I helped prove that selenium and vitamin E do not prevent prostate cancer. I have changed the course of prostate cancer research.”

Overall, that which remains the same in SELECT is our commitment to you. SELECT’s leaders are committed to conducting sound scientific research. Your Study Site staff is ready to answer your questions and to make your participation in SELECT a positive and fulfilling experience. So, you see, while the course of SELECT has changed, everything else remains the same!



News From The Four Ancillary Studies

PREADVISE - Prevention of Alzheimer’s Disease with Vitamin E and Selenium This is a partner study to SELECT. We will continue to follow PREADVISE participants each year, even though you no longer take the study supplements. We encourage you to continue your SELECT visits. By continuing these follow-up visits, PREADVISE participants can have their memory checked and their prostate health checked. We will continue to gain much knowledge when we look at the effects of the prior supplement use on your memory.

The discontinuation of study supplements does not decrease the value of the PREADVISE study. We would like to take this opportunity to thank you for your support as we keep up our efforts to defeat Alzheimer’s disease and other memory problems.

SEE - SELECT Eye Endpoints We thank all of you who are participating in SEE and look forward to your continued support. The SEE study is continuing and would like participants at sites participating in SEE to continue providing new reports of diagnoses of cataract and age-related macular degeneration (AMD). Many of these new reports, which will be confirmed by collecting your medical records, may have developed during the supplement-taking phase of SELECT. These events can then be included in the final analyses for cataract and AMD.

Study sites currently not participating in SEE are encouraged to seriously consider participation.

RAS - Respiratory Ancillary Study About 3,000 men at 16 SELECT sites across the country are also in the RAS. We thank these men and the staff at the RAS sites for all of their contributions to the study! Over the past few years, the men in RAS have answered questions about respiratory symptoms at their SELECT annual visits, and they have had their lung function measured several times. This information will allow us to answer questions about whether the vitamin E or selenium supplements in SELECT could be used to prevent lung diseases, particularly chronic obstructive pulmonary disease (COPD) and asthma.

Even though the RAS men are no longer taking the study supplements, all lung function tests will be completed as originally planned. Ongoing testing is very important, and we encourage men in the RAS to complete any remaining testing for RAS. Having information from the post-supplement time period may provide important insight about how the supplements affect lung disease.

The RAS is proud of the accomplishments of the study participants. The opportunity to find out if the study supplements prevent lung disease is an important one, especially since lung disease is the fourth leading cause of death in the United States.

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News From the Four Ancillary Studies (Continued from page 3.)

ACP - Adenomatous Colorectal Polyps Participants may be wondering how the decision to stop taking the study supplements affects the ACP. The answer is that it does not at all reduce our interest in collecting information. Not all SELECT sites are taking part in ACP, but at those sites that are taking part in ACP, participants will be asked at each six-month visit if they have had a colonoscopy or sigmoidoscopy procedure since their last clinic visit. It is very important that we continue to collect this information even though participants are no longer taking study supplements. Although neither selenium nor vitamin E, taken alone or in combination, have been found to prevent prostate cancer. This does not rule out the possibility that either agent, taken alone or together, may help to prevent colorectal cancer. We can gather invaluable information that will help us address this very important question.

We are extremely grateful to all those SELECT participants who have agreed to take part in the ACP Ancillary Study.

In Short...

SELECT Findings Published in Major Medical Journal

On December 9, 2008, **JAMA, The Journal of the American Medical Association** has published an on-line article detailing the recent SELECT findings. For your information and reference, it is available on the Journal's website. Check with your local library. *Reference: Lippman SM, Klein EA, Goodman PJ, et al. Effect of Selenium and Vitamin E on Risk of Prostate Cancer and Other Cancers. JAMA.*

We're Adding Something New to the CHOICE Newsletter

In response to your requests, beginning with the Spring 2009 CHOICE newsletter, we will include a listing of articles published about SELECT in scientific journals. We hope you will enjoy this new feature.



Have you checked out the SELECT website lately?

<http://www.crab.org/select>