

About Health TV with Jeanne Blake
Prostate cancer update
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JEANNE BLAKE: Welcome to *About Health TV*. We recently aired a program on *About Health TV* about prostate cancer, and during that program we talked about a clinical trial called the Select Trial that is available nationally at hospitals. We've been asked by the Veterans Administration to let viewers know about the Veterans Administration hospitals' role in that trial. We're joined by Dr. Mike Gazziano, who is the director of the VA component of the Select Trial, so we can learn a bit more about its availability and the role that the VA hospitals are playing nationally. Doctor, thanks for coming in.

DR. GAZZIANO: It's my pleasure.

JEANNE BLAKE: For the folks that didn't see the program about prostate cancer, could you tell us what the Select Trial is?

DR. GAZZIANO: The Select Trial is a large, randomized trial testing whether vitamin E or selenium would prevent prostate cancer.

JEANNE BLAKE: And let's review why there's some sense of hope that selenium and vitamin E can help in prostate cancer.

DR. GAZZIANO: Selenium and vitamin E play an important role in our antioxidant defenses, and two recent trials suggest very strongly that vitamin E and selenium might play a role in reducing the incidence of prostate cancer. There were two cancer prevention trials, one to test for the vitamin E against lung cancer and another to test whether selenium prevents skin cancer. Interestingly, they found that both studies, both agents reduced the chances of prostate cancer.

JEANNE BLAKE: The clinical trial is available to all American men, correct? Could you talk with us about who is welcome to inquire about this trial?

DR. GAZZIANO: Well, I think this is a very important trial for older men, because we know so little about how to prevent prostate cancer. This trial is available to all American men and Canadian men. There are centers both in the United States and Canada, over 400 sites. Typically it's the better-educated white Americans that volunteer for trials. This trial is a very important trial for African-

Americans because of their higher rates of prostate cancer. The VA has been asked to play a role because of our successes in being able to recruit minority men to large-scale trials.

JEANNE BLAKE: Why do you think that there is a disproportioned participation from white males in clinical trials, and does that prove true over other diseases?

DR. GAZZIANO: It does. It's something that's fairly consistent. I think that the place that people get their care and the faith they have in healthcare providers often influences whether or not you would want to be involved in a large-scale trial. More educated people tend to be involved in trials. In this particular trial, it's so important that we get a broad sector of the population that we're making a strong appeal to all races, all minority groups to be a part of the trial.

JEANNE BLAKE: And of course African-American men are disproportionately affected by prostate cancer and more likely to die should they be diagnosed with the disease.

DR. GAZZIANO: Yes. The rates of prostate cancer are higher among African-American men, and people who present with prostate cancer who are African-Americans usually present with a later stage of the disease, which is often more fatal.

JEANNE BLAKE: Okay. Let's try to take some of the mystery out of what this trial might involve. If I am a man who wants to participate, first of all, what will it require of me?

DR. GAZZIANO: You'll come to the center and be interviewed by the center staff and determine whether or not you're eligible for the trial. For an African-American, you have to be over the age of 50, for white Americans you have to be over the age of 55, and that's because the prostate cancer rates occur at slightly different levels and there's two age groups. Then you'll be interviewed about certain eligibility criteria. Things that would preclude you from being in the trial include existing prostate cancer, because this is a prostate cancer prevention trial, if your blood pressure is too high, if you're on blood thinning medications you can't be in the trial. If you don't have any exclusion criteria, you'll be entered into the trial and given a three-month supply of the study pills, and then you'll be asked to come back periodically during the year.

JEANNE BLAKE: That's a big question. How often?

DR. GAZZIANO: There are two annual visits to the clinic center, where you'll be asked a series of questions, particularly about how well you're taking your vitamin pills. I think it's important to point out that not everybody will get the active vitamin E. Half the population will get the placebo, or the dummy pill, and half will get the vitamin E or the selenium.

JEANNE BLAKE: I'm just curious. Have you decided to take these vitamins knowing so much about how they can prevent cancer?

DR. GAZZIANO: Well, I think the important message right now is, we don't know if they prevent cancer, and that's what the trial is designed to test.

JEANNE BLAKE: But they have shown to be effective against other cancers.

DR. GAZZIANO: Well, the early results suggest that they may play a role, and what was interesting in the trials that we mentioned earlier is that it didn't prevent the cancers they thought it might, and in looking at some other cancers, there was a surprising reduction, particularly prostate cancer but also colon cancer. What we don't know is, was that just a play of chance? Was the cancer reduction not really the result of taking the vitamin E or the selenium? So this trial is designed to test whether or not in fact it was the vitamin E or the selenium that prevents the cancer. Until we finish this trial, we really won't know the answer, so at this point we don't recommend taking vitamin E or selenium to our patients as a preventative measure. I think that it's very reasonable to enroll in this trial. You'll have a three-quarters chance of being on one or both of the study agents.

JEANNE BLAKE: There's no cost involved?

DR. GAZZIANO: There's no cost involved.

JEANNE BLAKE: And it really does not require that much time.

DR. GAZZIANO: No, it doesn't. The big commitment is to taking these vitamin pills on a daily basis.

JEANNE BLAKE: We all know what that's like. I bought a multivitamin about a week ago, and I think I've taken it once. And now I have a cold, so there you go.

DR. GAZZIANO: That's the critical element. It's that you need to be able to make a commitment. The trial will go on. This is one of the largest prevention trials of its kind, and it will be conducted among 32,400 people and will go on for the next 12 years. And that's how long it takes for us to tell whether something ...

JEANNE BLAKE: So someone will have to make the commitment for the 12 years to be followed at some regular interval?

DR. GAZZIANO: That's right. Twice a year.

JEANNE BLAKE: That's another important footnote.

DR. GAZZIANO: The recruitment is, for five years we'll be recruiting people. So the first person in will be on it for 12 years and the last person will be on it for seven.

JEANNE BLAKE: I think it's very important to mention, because this program does air in other cities, that you have the trial available in Detroit, in Phoenix, in Denver, and here in Boston, and in locations throughout Ohio.

DR. GAZZIANO: That's right. There are locations in all the cities you mentioned and throughout the country. You can find out where the site closest to you is by calling an NCI, National Cancer Institute, number, 1-800-4CANCER, and they'll give you the location of the site closest to you.

JEANNE BLAKE: All right. Easy number to remember.

DR. GAZZIANO: I do want to point out that there are 48 VA hospitals around the country that are participating. The VA Boston is one of those centers, and you can call your local veterans hospital and find out if they are participating.

JEANNE BLAKE: Terrific. Doctor, thank you for taking time to come in to tell us about the Select Trial. We appreciate it.

DR. GAZZIANO: It was my pleasure.

JEANNE BLAKE: And thank you for joining us on this edition of *About Health TV*. I'm Jeanne Blake. I'll see you next time.

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