INSIDE THIS ISSUE

Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

APRIL 2010

NEW PROSTATE CANCER SCREENING GUIDELINES

By Dr. Len Lichtenfeld, Deputy Chief Medical Officer, National Office, American Cancer Society

In the words of that great philosopher, Yogi Berra, "This is like déjà vu all over again."

Maybe yes, maybe no.

If you assume that the new guidelines for the early detection of prostate cancer released today by the American Cancer Society don't offer anything different compared to the last major revision of the guidelines in 2001, then you may be missing some important messages about prostate cancer screening. And you may miss what I consider the most important message of all: prostate cancer is so common in men age 50 and over that finding it by prostate cancer screening may be nothing more for most men than a fortuitous "random walk." As I learned myself, even with a perfectly normal PSA there is a real possibility that you have prostate cancer. Whether you need to find it or not is the heart of the issue.

Prostate cancer is clearly a major health issue in the US. The American Cancer Society estimated that in 2009 (the latest year for which statistics are available) there were 192,280 men diagnosed with prostate cancer, mak-

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WHICH MEN SHOULD TAKE FINASTERIDE TO REDUCE PROSTATE CANCER RISK?

In a study conducted by the Memorial Sloan-Kettering Cancer Center (MSKCC) in New York, a detailed analysis of the finasteride prostate cancer reduction effect was conducted in an attempt to define who should take the drug to prevent future prostate cancer development. Finasteride, a 5-alpha-reductase inhibitor, has been shown to be an effective chemopreventive agent for prostate cancer. In the Prostate Cancer Prevention Trial (PCPT), finasteride reduced the risk of prostate cancer by close to 25%. Despite this landmark finding, use of finasteride to prevent cancer in the community remains low.

One reason for initial caution was an apparent increase in high-grade disease in men taking finasteride – 37% of men taking finasteride versus 22% taking placebo had high biopsy (called Gleason) grades. However, subsequent research has suggested that the relationship between finasteride and high-grade cancer was an artifact related to differential sampling of high-grade disease in small prostate volumes.

The low use of finasteride in the community may also be because most men are at low risk of morbidity or death

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ROBOT-ASSISTED SURGERY IS NO BETTER TREATMENT FOR PROSTATE CANCER

Men tend to like shiny new machines. And that may partly explain the growing popularity of robot-assisted surgery for treating prostate cancer. But a new study, released this week, has found that the state-of-the-art robotic procedure really isn't substantially better than the old-fashioned method for removing the male gland when it has become cancerous.

Researchers at Memorial Sloan-Kettering Cancer Center in New York looked at the outcomes of 6,000 men who had their prostates removed through a variety of different surgical techniques. Some patients had a traditional open radical prostatectomy (RP), in which the surgeon makes a six-inch-long cut through the abdomen to gain access to the walnut-sized gland. Others had the newer laparoscopic RP, in which extra-long medical instruments – including a camera scope – are inserted into the belly through small keyhole incisions.

And for a subset of the laparoscopic patients, surgeons also used the latest robotic instruments, which are remotely controlled by way of a 3-D visual system.

Despite all the hoopla regarding

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AMERICAN CANCER SOCIETY UPDATES PROSTATE CANCER SCREENING GUIDELINES

Update Reaffirms the Importance of Shared Decision-Making

Newly updated prostate cancer screening guidelines from the American Cancer Society reaffirm the recommendation that men should discuss the uncertainties, risks and potential benefits of screening for prostate cancer before deciding whether to be tested. The update is the first since 2001 and was done as part of the Society's regular guidelines update process. It included a series of systematic reviews focusing on the latest evidence related to the early detection of prostate cancer, screening test performance, harms of therapy for localized prostate cancer, and shared and informed decision making in prostate cancer screening.

The guideline is published online in advance of print publication in *CA: A Cancer Journal for Clinicians*. The updated guidelines include these recommendations:

- Asymptomatic men who have at least a ten-year life expectancy should have an opportunity to make an informed decision with their health care provider about screening for prostate cancer after receiving information about the uncertainties, risks, and potential benefits associated with screening.
- Men at average risk should receive this information beginning at age 50. Men at higher risk, including African American men and men with a first degree relative (father or brother) diagnosed with prostate cancer before age 65, should receive this information beginning at age 45. Men at appreciably higher risk (multiple family members diagnosed with prostate cancer before age 65) should receive this information beginning at age 40.
- Men should either receive this information directly from their health care providers or be referred to reliable and culturally appropriate sources.
- Patient decision aids are helpful in preparing men to make a decision whether to be tested.
- Prostate cancer screening should not occur without an informed decision making process.
- Asymptomatic men who have less than a ten-year life expectancy based on age and health status should not be offered prostate cancer screening.
- For men who are unable to decide, the screening decision can be left to the discretion of the health care provider, who should factor into the decision his or her knowledge of the patient's general health preferences and values.

"Two decades into the PSA era of prostate cancer screening, the overall value of early detection in reducing the morbidity and mortality from prostate cancer remains unclear," said Andrew M. Wolf, MD, Associate Professor of Medicine at the University of Virginia Health System and Chair of the Advisory Committee. "While early detection may reduce the likelihood of dying from prostate cancer, that benefit must be weighed against the serious risks associated with subsequent treatment,

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ROBOTIC SURGERY

(Continued from page 1)

laparoscopic surgery – with or without robotic assistance – the study found few significant differences in outcomes. Patients tended to bleed less and recover faster with the keyhole surgery. But in terms of postoperative complications within a year of the surgery – including incontinence resulting from tissue damage – the level of risk appears to be equal with the different procedures. (The current study did not evaluate the risk of impotence or erectile dysfunction because it usually takes more than a year to determine if there is permanent damage).

But the newest procedure is certainly more expensive. The robotic equipment – called the da Vinci Surgical System – costs about $4.5-million. The surgical instruments must be changed frequently, adding more than $3,000 to the cost of each procedure.

William Lowrance, the lead author of the study published in the *Journal of Urology*, noted that many US medical institutions have been heavily promoting their high-tech procedures – especially the use of robotic-assisted instruments. Numerous Canadian hospitals have also acquired the equipment and now some men won't agree to the surgery unless it's done robotically.

In an editorial accompanying the study, Yair Lotan of the University of Texas Southwestern Medical Center in Dallas, writes that the major factor affecting the success of any operation is the skill of the surgeon.

"I think the misconception is that the robot somehow makes you a better surgeon – it really doesn't," Dr. Lotan said in an interview. Robotics may provide greater flexibility of movement, but they still have to be guided by the surgeon's hands, he added.

Globe and Mail, 25 February 2010

Wonder what's happening in local support groups?

Read the

CHAPTER NEWS!

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AUA RESPONDS TO AMERICAN CANCER SOCIETY GUIDELINE FOR THE EARLY DETECTION OF PROSTATE CANCER

On 3 March 2010, the American Cancer Society issued its new Guideline for the Early Detection of Prostate Cancer. The American Urological Association (AUA), which represents more than 16,000 urologists and urologic health professionals worldwide, issued the following statement in response to the new ACS document. The statement is attributable to AUA President Anton J. Bueschen, MD.

"The American Urological Association applauds the American Cancer Society (ACS) for its new guidance statement on prostate cancer detection. We concur that informed consent – including a discussion between physician and patient about the risks and benefits of testing – is a key part of one's decision to be tested for prostate cancer. It is equally necessary that patients receive reliable information from culturally appropriate sources.

However, the new ACS statement may not fully characterize the potential benefits of an individualized approach to assessing risk in men considering the risk and benefits of early detection strategies and may cause significant confusion for patients. The AUA feels there is no single PSA standard that applies to all men, nor should there be. Part of informed consent is giving patients as much information about their personal risk as is available. Applying population-based cut points while ignoring other individual risk factors (such as age, ethnicity, family history, previous biopsy characteristics, etc.) may not give a patient the most optimal assessment of his risk, including the risk of high grade disease.

Prostate cancer testing is an individual decision that patients should make together with their doctor. The AUA believes that all men, with a life expectancy of 10 years or more, should have a baseline PSA test at the age of 40. Physicians should determine rescreening intervals for each patient based on PSA (and, on occasion on its change over time). Likewise, the decision to proceed to prostate biopsy should be based not only on elevated PSA and/or abnormal DRE results, but should take into account multiple factors including free and total PSA, patient age, PSA velocity, PSA density, family history, ethnicity, prior biopsy history and comorbidities.

Although prostate cancer risk correlates with serum PSA, there is no PSA value below which a man may be reassured that he does not have biopsy detectable prostate cancer.

AUA is in full agreement with ACS that current early detection strategies need to be refined and better validated. It is hoped that new biomarkers will be identified which better distinguish between indolent and aggressive prostate cancer, sparing the former from unnecessary testing and giving the latter a better chance of survival.

In April 2009, the AUA issued its new Best Practice Statement on Prostate-Specific Antigen, which can be viewed at <www.auanet.org/content/guidelines-and-quality-care/clinicalguidelines/main-reports/psa09.pdf>.

AUA news release, 3 March 2010

HIGH-FIBER FOODS BLOCK CANCER PATHWAYS

Why do people who eat high-fiber diets typically have lower incidence of certain cancers? Researchers at the Univ. of Colorado Cancer Center may have an explanation after discovering that a nutrient called inositol hexaphosphate (IP-6) blocks a pathway some cancer cells use to multiply, recruit blood vessels and keep from dying.

IP-6, also known as phytic acid, is found in high concentrations in whole grains and legumes. It's also a currently available nutritional supplement.

Mallikarjuna Gu, a research associate of Pharmaceutical Sciences Dept. at the Univ. of Colorado School of Pharmacy, discovered that treating prostate cancer cells in a Petri dish and those transplanted into mice with IP-6 stopped the cancer from growing.

Upon further investigation, he discovered that IP-6 disrupts the P13K-Akt pathway, which is shown to play a major role in the development and progression of prostate cancer, breast cancer and colorectal cancer.

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COMPLEX NEW GUIDELINES FROM MULTIPLE ORGANIZATIONS CONFUSE MEN ABOUT PROSTATE CANCER SCREENING

Members of America's Prostate Cancer Organizations are concerned that the issuance this morning of yet another set of new guidelines on screening for prostate cancer is only adding to the confusion most men already feel about whether they should or shouldn't be tested for the most common form of cancer in American men.

"It is time for us all to come together and make one, straightforward recommendation about screening and early detection of prostate cancer that is easily understood by men and their doctors," said Thomas Kirk, President & CEO of Us TOO International Prostate Cancer Education and Support Network.

"In the past 12 months we have seen new guidance on prostate cancer screening from the American Urological Association (a professional society), the National Comprehensive Cancer Network (a network of cancer centers), and now the American Cancer Society (a cancer nonprofit)," stated Skip Lockwood, President of ZERO – The Project to End Prostate Cancer. "Each set of guidelines is complex, and the details in each set of guidance are all slightly different."

America's Prostate Cancer Organizations, which seek to act in the best interests of men at risk for prostate cancer and those already diagnosed with this disease, believe that it is high time that the various groups work together to issue one, simple guidance document for men and their families and another for the primary care community. Such guidance should represent a consensus position of the US professional societies and other stakeholders on the risks and benefits of screening for prostate cancer, as opposed to the viewpoints of selected groups of specialists.

"These guideline discrepancies only add to the confusion around two key issues – when to be screened and what to do with the screening results," said Wendy Poage, President of the Prostate Conditions Education Council.

"By collectively issuing clear guidelines, we can finally address these questions and encourage men to take appropriate steps to safeguard their health."

"There appears to be significant overlap between the recommendations of the various groups issuing these differing guidelines," noted Scott T. Williams, Vice President of Men's Health Network. "The members of America's Prostate Cancer Organizations are more than willing to work closely with the interested sectors to help to develop standard and simple guidelines that can be universally promoted to men and their families and to the provider community."

About America's Prostate Cancer Organizations: Prostate cancer is the most prevalent form of cancer among American males. Nearly 200,000 men will be diagnosed with prostate cancer in 2010, and about 28,000 will die from this disease. This group of independent, not-for-profit organizations cooperates to foster the development of policies that support the early detection of clinically significant prostate cancer, the effective treatment of men with this disease, and the appropriate education of all men who may be at risk for this disease.

The above statement has been issued on behalf of and endorsed by:

Malecare Prostate Cancer Support
Men's Health Network
National Alliance of State Prostate Cancer Coalitions
Prostate Cancer Foundation
Prostate Cancer International
Prostate Conditions Education Council
The Prostate Net
Us TOO International Prostate Cancer Education and Support Network
Women Against Prostate Cancer
ZERO – The Project to End Prostate Cancer

PRNewswire-USNewswire, 3 March 2010

SEEKING VOLUNTEERS FOR CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PEER REVIEW PANELS

The US Army Medical Research and Materiel Command has requested nominations from Us TOO International for consumer representatives to participate on the Department of Defense prostate cancer scientific peer review panels. Currently, they are seeking nominations from prostate cancer organizations nationwide, and hope that survivors within the Us TOO network will participate in this worthwhile endeavor.

Nominees must be endorsed by Us TOO and must be:

- A survivor of prostate cancer;
- An active participant in a prostate cancer–related organization (support, outreach, advocacy);
- A high school graduate or have met GED requirements;
- Able to read and write English;
- Able to demonstrate an interest in extending his personal scientific knowledge;
- Willing and able to represent the views of his community rather than his personal perspective;
- Able to access a computer with a connection to the Internet.
- Able to devote time for proposal review and attend one 3-day meeting in Washington, DC.

To obtain a letter of endorsement from Us TOO International, you must submit your completed application form by Monday, April 19th to: Tom Kirk, President & CEO, Us TOO International, 5003 Fairview Avenue, Downers Grove, IL 60515-5286, Fax: 630-795-1602, Email: tom@ustoo.org.

For more information and to obtain the application form, visit: <www.ustoo.org/UsTOOAdvocacyAlertV11.asp> or call Jackie at (800) 808-7866.

HIGHER DOSE RADIATION MAY BE BETTER IN PROSTATE CANCER

For early-stage prostate adenocarcinoma, high-dose conformal radiation (RT) appears to achieve better results than conventional doses, researchers report in a 1 February 2010 online paper in the *Journal of Clinical Oncology*.

"The long-term data from this study confirm that higher doses of RT are more likely to durably eradicate localized prostate cancer than more conventional doses," stated lead author Dr. Anthony L. Zietman of Massachusetts General Hospital in Boston. "As proton beam was used in this study, it also confirms that proton beam is one excellent way to deliver these more effective, higher doses."

Dr. Zietman and colleagues randomized 393 men to receive a total dose of either 70.2 or 79.2 Gray equivalents. After a mean follow-up of 7.9 years, men in the high-dose group were significantly less likely to experience local failure (hazard ratio = 0.57). In the 227 patients with low-risk disease, the 10-year biochemical failure rates were 7.1% in the high-dose group and 28.2% in the conventional dose group.

There was also a strong trend in the 144 intermediate risk patients (30.4% versus 42.1%). Initially, none of the patients had androgen suppression therapy. Later, however, 6% of high-dose patients and 11% in the conventional-dose group required androgen deprivation for local recurrence.

Despite the apparent success of the approach, Dr. Zietman pointed out that the study does not "answer the question of whether or not proton beam is a superior technique when compared with the alternatives such as intensity modulated RT or brachytherapy." Also, there was no difference between the groups in overall survival (78.4% vs. 83.4% in the high-dose and the conventional dose groups).

In an accompanying editorial, Dr. W. Robert Lee of Duke University Medical Center points out that active surveillance may be a better alternative. "In fact," he concludes, "for the 73-year-old man with low-risk prostate cancer, the best dose may be 0 Gy."

NEW ACS GUIDELINES *(Continued from page 2)*

particularly the risk of treating men for cancers that would not have caused ill effects had they been left undetected."

The authors say in light of ongoing uncertainties, including the uncertain balance between benefits and risks, involving men in the screening decision is crucial. "With these newly updated recommendations, the American Cancer Society places even stronger emphasis on shared decision making between clinicians and patients," said Otis Brawley, MD, chief medical officer of the American Cancer Society. "The decision whether to screen should be made with the help of a trusted source of regular care. Men without access to regular care should not be tested unless high-quality informed decision-making as well as appropriate counseling and follow-up care for those who test positive can be assured. Without those, community-based screening should not be initiated."

"Previous guidelines from the American Cancer Society and other organizations have discussed the importance of informed decision making for men who are considering prostate cancer screening, however this update is the first to provide details regarding what information about screening is needed for informed decision-making to occur," said Alan G. Thorson, MD, FACS, volunteer president of the Society. "For that reason, the updated ACS guidelines delineate the core elements of information necessary for men to engage meaningfully in this decision, and encourage inclusion of this information in patient discussions and decision aids."

The guidelines also includes updated clinical recommendations regarding screening tests, intervals, and follow up of abnormal results for those men who choose to be screened after considering the possible benefits and risks. The guidelines acknowledge the limited contribution of digital rectal exam (DRE) to prostate cancer early detection and state that screening can be performed using PSA with or without the DRE. The guidelines recommend annual screening for men whose PSA level is 2.5 ng/ml or higher, but state that screening intervals can be safely extended to every two years for men whose PSA is less than 2.5 ng/ml.

The guidelines affirm that a PSA level of 4.0 ng/ml or higher remains a reasonable threshold to recommend referral for further evaluation or biopsy for men at average risk of developing prostate cancer; for PSA levels between 2.5 and 4.0 ng/ml, health care providers should consider an individualized risk assessment that incorporates other risk factors for prostate cancer in the referral decision.

The update included a complete review of the evidence. The American Cancer Society's Prostate Cancer Advisory Committee, composed of independent researchers, clinicians and lay people, examined systematic reviews done by scientific experts at Emory University, Rollins School of Public Health, met to hear presentations by experts both on the Committee and by invited outside experts, and deliberated the evidence before making its final recommendations. The guideline underwent peer review before going before the American Cancer Society volunteer Board of Directors for approval.

The authors conclude by noting the urgent need for better ways to detect and treat early-stage prostate cancer, particularly the need to distinguish between cancers that do not require treatment and those that are aggressive, to help "tip the balance clearly in favor of screening. Until that time, however, it will remain incumbent on health care providers and the health care system as a whole to provide men with the opportunity to decide whether they wish to pursue early detection of prostate cancer."

American Cancer Society, 3 March 2010

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DR. LEN LICHTENFELD'S COMMENTS ON NEW ACS GUIDELINES *(Continued from page 1)*

ing it the most common form of cancer in men. Deaths from prostate cancer in the United States for 2009 were estimated to be 27,360, underlining the fact that many more men are diagnosed with the disease than die from it.

That's the relatively easy part of the discussion. The hard part – as has become all too obvious to many over the past year through the controversy caused by the release of two studies that were supposed to answer the question of whether or not detecting prostate cancer early really made a difference in survival – is whether, well, prostate cancer screening really makes a difference in survival.

So controversies exist about what to do regarding the early detection of prostate cancer in men and whether or not getting a blood test called a prostate specific antigen (or PSA) with or without a rectal examination is something that men should do to save their lives.

Lo and behold, the evidence isn't clear on this topic, despite the fact that we have been vigorously testing men with PSA tests for about the past 20 years, and are busy every day in this country lopping out and radiating prostates to treat prostate cancer, leaving many of those men with serious long term consequences like decreased sexual function and urinary incontinence.

Given all of this uncertainty and inconsistency of the evidence, you would rightly ask, "What does the American Cancer Society recommend that men should do when it comes to that annual rite of a PSA blood test to find prostate cancer early?"

So here are the major recommendations from the guidelines:

- Asymptomatic men who have at least a ten-year life expectancy should have an opportunity to make an informed decision with their health care provider about screening for prostate cancer after receiving information about the uncertainties, risks, and potential benefits associated with screening.
- Men at average risk should receive this information beginning at age 50. Men at higher risk, including African American men and men with a first degree relative (father or brother) diagnosed with prostate cancer before age 65, should receive this information beginning at age 45. Men at appreciably higher risk (multiple family members diagnosed with prostate cancer before age 65) should receive this information beginning at age 40.
- Men should either receive this information directly from their health care providers or be referred to reliable and culturally appropriate sources.
- Patient decision aids are helpful in preparing men to make a decision whether to be tested.
- Prostate cancer screening should not occur without an informed decision making process.
- Asymptomatic men who have less than a ten-year life expectancy based on age and health status should not be offered prostate cancer screening.
- For men who are unable to decide, the screening decision can be left to the discretion of the health care provider, who should factor into the decision his or her knowledge of the patient's general health preferences and value

Let me emphasize a couple of key points in these guidelines, in an effort to reduce confusion over what they say and what they do not say.

Most important, the American Cancer Society does not recommend routine screening for prostate cancer, and has not since 1997. There is simply insufficient and conflicting evidence to say whether or not PSA tests really make a difference and save lives. Some evidence says, "Yes it does," other evidence says, "No it doesn't," and some evidence is still too early to say for certain one way or another.

Bottom line, this picture is not clear so we can't say yes or no as to whether or not screening is right for you. So what do you do?

You and your health professional need to have a talk about the pros and cons of screening. You need to understand the possible benefits and harms, and what the evidence shows. Then you can make an informed decision about what is right for you. You may weigh the evidence and conclude that you want to be screened with a PSA test, or you may weigh the evidence and say that you don't. And if you can't make up your mind, the guidelines recommend that your health professional take your personal considerations into account and make the decision for you.

"But wait a minute," you say. "I go to my doctor or other health professional for an office visit these days, and I am lucky if I get to say hello before she/he moves on to the next patient. How the heck are we going to have that discussion? Great theory; lousy practice."

That's where the modern age of technology comes in.

There are a number of valuable decision aids available on the Internet, which have been shown to make the process more reasonable and efficient – and allow you to move at your own pace in learning about prostate cancer screening benefits and risks. You will need an internet connection, or you can call us at 800-ACS-2345 and we can offer you some help and guidance. Information is posted on our website today at <www.cancer.org>.

"But wait another minute: my local hospital has free screening. Isn't that a reasonable thing to do? Just go to my local grocery store parking lot, find the PSA van when it is there and get a test? Why shouldn't I do that?" you might ask.

Here's where we are probably at odds with many people who believe they are doing good by giving men mass screening in convenient locations.

Our guidelines are pretty straightforward on that one: unless you are someone who simply has no other access to medical care because you can't afford it, mass screening doesn't offer individualized counseling and education about the benefits and risks of PSA testing, so it should not be offered. And for communities that are disadvantaged, an effort must be made to provide that education and follow-up.

In other words, in our opinion, mass screenings at health fairs, or local parking lots or wherever are not a good idea. They certainly don't meet the recommendations in our guidelines

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DR. LEN LICHTENFELD'S COMMENTS ON NEW ACS GUIDELINES *(Continued from page 6)*

that men have a direct discussion with their health care professional to discuss benefits, risks and harms of screening for prostate cancer. And let's be clear: although the benefits are uncertain, the risks and harms of treatment are real.

There is another "wrinkle" to the new guidelines that will be important for men to know, and it may also be somewhat controversial.

Most men who get PSA testing believe they should have the test every year. Putting aside the issue of whether or not PSA testing is right for you, the reality is that the evidence does not support the need for doing the blood test annually. Instead, if your PSA is below 2.5, the new guidelines recommend that you have the test every other year in the event you choose to pursue screening for prostate cancer.

The guidelines also maintain a recommendation that a PSA of 4.0 or greater needs to be evaluated. Over the past number of years, however, there has been a lot of discussion about the true "normal" level of PSA which requires further evaluation by a urologist. As a result of that discussion, the guidelines recommend that doctors and patients make an individual decision as to whether a PSA between 2.5 and 4.0 requires further evaluation. Those are traditionally normal values, but you and your doctor should discuss whether or not she/he thinks you need to be looked at further by a specialist.

One of the factors that we used to use in the past to make a decision whether or not that evaluation was something called PSA velocity. In simple terms, PSA velocity refers to how quickly the PSA level increases year over year. If it's too fast, a doctor was supposed to recommend evaluation for possible cancer. If it was a small steady increase, then you could wait before moving on to ultrasound and biopsy.

In the new guidelines, the expert panel concluded that PSA velocity simply isn't useful enough to make a decision one way or the other. To some degree, that is a function of the PSA test itself which can vary considerably from test to test and day to day for a number of reasons. The PSA test is simply not accurately reproducible day to day, so its value is not as precise a number as some people believe. So whether or not your PSA is going up at a certain pace doesn't help make the decision whether or not you may have prostate cancer.

Why are we having all of this trouble figuring out whether or not PSA works? To some degree – as already mentioned – it is simply a matter that the evidence is in conflict at this time. Maybe with another couple of years of follow-up on the major studies we will have more clarity in what they are trying to tell us. But right now, we are not there.

There is another and very important bit of background, and that is that many of us – even those with perfectly normal, low value PSA tests – harbor cancer in our prostate glands. We get a normal PSA blood test, think we are home safe for another year, yet deep inside the cancer is lurking. The good news is that most of these cancers are indolent, that is, they won't cause us a problem. But for some of us, they may be high grade and not yet "visible" with the PSA test.

The reality is that prostate cancer is a disease of aging, one that actually starts at a very young age and continues to increase in frequency as we go from 40 to 50 to 60 and on. In simple terms, if you are a man, there is a possibility if not a probability (depending on your age) that you have a cancer in your prostate.

Let's talk real life here for a moment.

Yours truly has been blessed with a very normal PSA value (less than 1.0) for many years. Last year it shot up, and being the consummate professional that I am, I was scared. A trial of antibiotics, a repeat test, and – good news – the PSA dropped a bit.

Being the typical doctor that I am, I didn't find the time to go back and get my PSA repeated last August. Instead, I decided to let the anxiety build and build and build until a couple of days ago when I finally relented and got the repeat PSA test.

The good news was that it was back down to its very normal level of past years. And, to be truthful, I was relieved. That relief only lasted for a day, since as I prepared this blog I decided to take advantage of one of the tools contained in the guideline which lets a man take his specific information (including his PSA and body mass index among other data) and make an estimate of whether or not he has cancer in his prostate.

What I found was instructive to me and I suspect may be to you as well, since despite my very, very normal PSA for a man of my age, my risk of having a prostate cancer is 14.1%. The risk of having a biopsy-detectable high-grade prostate cancer (that's the bad kind) is 1.3%. And that would be the same percentage for any other man out there who is my age, my size, and has a low PSA.

So now what do I do?

Do I continue getting PSAs every year, the evidence notwithstanding that it may not do any good? Or do I go and get a prostate biopsy just for the fun of it?

My case isn't unique, because the reality is that for many of you men out there, if we stuck your prostate often enough with enough biopsy needles, we would stand a reasonable chance of finding cancer in your gland as well.

That is the crux of the dilemma: we have a blood test that is modestly accurate, but we don't know if it really makes a difference. And a normal value gives us false comfort that we do not harbor prostate cancer in our bodies, when in fact that may not be the case – especially as we get older.

So it's back to square one: you make your decision on whether or not you want to be screened based on your own values and what type of person you are. But you must have the discussion and make the decision, since having your doctor say "just do it" is no longer sufficient unless you are part of the process.

No, we haven't made the situation any easier. But we have told you what the evidence currently shows. Now it is up to you to take the next step and have the conversation.

<www.cancer.org>
Doctor Len's Cancer Blog
3 March 2010

ASK DR. SNUFFY MYERS

Editors' note: In the spirit of information sharing, we have invited certain physicians and others to provide comments and opinions for Us TOO's *HotSheet.* It is our desire to enrich the content of the *HotSheet* to empower the reader. Each piece contains the opinions and thoughts of its author and is not necessarily those of Us TOO International.

Dear Dr. Myers,

In your newsletters you mention the interaction of some supplements and common PCa drugs used to treat prostate cancer. How do we find a list of these interactions so we can share the information with men in our chapters?

I know of no comprehensive listing. The most important interactions involve changes in the way your body handles drugs. The liver is involved in destroying more than half of all prescription drugs and many supplements. The recommended dose of each agent is selected with that in mind and designed to deliver enough drug but avoid liver destruction. Anything that increases or decreases the ability of the liver to destroy drugs can cause problems by either causing you to have too much or too little of a drug. For many drugs, a toxic dose is just twice the recommended dose, so there is often not much of a margin for error.

The most important liver pathway for drug destruction uses a protein called CYP3A4. Yes, I know this is not exactly a patient-friendly name, but that is the way it is. Wikipedia has an excellent discussion of this protein and that article contains a comprehensive list of drugs involved <http://en.wikipedia.org/wiki/CYP3A4>. The Physicians Desk Reference (PDR) also contains this information for most prescription drugs. The most important supplements that interact with this protein are St. John's Wort, grapefruit, and silymarin (milk thistle).

Warfarin (Coumadin®), the blood thinner, is another drug that interacts with a wide range of other drugs, supplements, and foods. Since this drug lessens the ability of the blood to clot, these interactions can cause you to bleed to death on one hand and or have a serious blood clot on the other. Family physicians prescribing warfarin monitor blood clotting as a safety measure and are usually very knowledgeable about potential interactions. Resveratrol markedly enhances blood thinning of warfarin. This is new and not widely known. The maximum dose of warfarin on resveratrol can be as low as 1-3 mg. The FDA has a nice web posting on this subject <http://dietary-supplements.info.nih.gov/factsheets/cc/coumadin1.pdf>.

Acetaminophen (Tylenol®) or is the other drug I really worry about. Acetaminophen overdose will cause lethal liver damage and is one of the most

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HIGH-FIBER FOODS

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Gu works in the lab of Rajesh Agarwal, co-leader of UCCC's AMC Cancer Prevention and Control Program and professor of Pharmaceutical Sciences at the Univ. of Colorado School of Pharmacy. Agarwal studies natural substances that can prevent cancer from happening or keep it from returning once treatment is complete.

Agarwal says the research points out how IP-6 works in cells, and may explain why people who eat diets high in fiber – and specifically high in legumes – seem to have a lower risk of cancer or signs they may develop it .

"Now, we have to do clinical trials to find out how much IP-6 is needed to have both preventive and therapeutic effects." Agarwal is collaborating with UCCC prostate cancer physicians Michael Glodé and Thomas Flaig to design clinical trials of various natural products, to test how they work in prostate cancer.

"We may see if we can alter the speed of prostate cancer development in men who are at high risk by giving them this supplement or having them change to a diet high in fiber and legumes," Agarwal says. "And we may also explore combining IP-6 with traditional chemotherapy to see if we can get a synergizing effect—if the supplement makes the cancer drugs work better."

The discovery is published in the journal *Cancer Research*.

Laboratory Equipment, 26 February 2010

USING NITROGLYCERIN TO TREAT PROSTATE CANCER SHOWS POTENTIAL TO HALT DISEASE

Treatment of prostate cancer using a very low dose of nitroglycerin may slow and even halt the progression of the disease without the severe side effects of current treatments, Queen's University researchers have discovered.

The findings are the result of the first-ever clinical trial using nitroglycerin to treat prostate cancer. The 24-month, Phase II study targeted 29 men with increasing levels of prostate-specific antigen (PSA) following prostate surgery or radiation. PSA levels are a key predictor of cancer progression.

"We were very excited to see a significant slowing in the progression of the disease as evidenced by the men's PSA levels, and to see this result in many of the men who completed the study," says Robert Siemens, leader of the study and a Professor of Urology at Queen's University and urologist at Kingston General Hospital.

The researchers are encouraged by the results, particularly because safe and effective treatments for men with rising PSA levels following surgery or radiation are limited. Of patients who have undergone radical prostatectomy and/or radiation treatment, it is estimated that 30 to 50 percent will experience a recurrence of cancer. They note that further testing needs to be done to confirm the results of this very small study.

The men were treated with a low-dose, slow-release nitroglycerin skin patch and their PSA levels monitored. Of the 17 patients completing the study, all but one showed a stabilization or decrease in the rate of cancer progression estimated by their PSA doubling time.

Nitroglycerin has been used at significantly higher doses for more than a century to treat angina (chest pain). This trial was based on a key finding from pre-clinical research carried out at Queen's, which showed that decreases in nitric oxide play an important role in tumor progression and that this progression can be stopped by low-dose nitroglycerin.

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AMERICAN CANCER SOCIETY – IGNORANCE IS BLISS WHEN IT COMES TO PROSTATE CANCER

By Rick Lyke

The American Cancer Society is telling men to pull up their pants, roll down their sleeves and not to worry about that prostate cancer thing.

In a guidance issued on Wednesday, the group – which carries a huge amount of weight with physicians and patients – basically said American men are better off not knowing if they have prostate cancer. Citing difficulties in determining who should be treated when cancer is found, the American Cancer Society (ACS) has decided it is better for some men to die from prostate cancer than for others to have their anxiety levels go up because they receive an inflated prostate specific antigen (PSA) test result due to prostatitis or some other medical condition.

The ACS has long lagged behind a number of prostate cancer organizations that advocate for earlier testing as a key to early detection. When prostate cancer is detected in the early stages, treatment has a far greater chance for success. Most groups focused on fighting prostate cancer tell men to get tested for prostate cancer for the first time at age 40. For people with a family history of prostate cancer or in a high risk group, such as African American men, the suggestion is that testing should start at 35 years old.

Few men really welcome the prospect of a digital rectal exam. So when the ACS says wait until you are 50 years old (45 for African Americans and 40 for men with multiple family members that have had the disease before 65 years old), that's what most men will gladly do. When they say that the tests are not always perfect, that sends a "why bother" message to men.

More troubling is the confusing recommendations the ACS provides about the PSA blood test. The PSA test started being used widely in the 1990s. The early warning the test provides, along with campaigns aimed at getting men to have regular exams, has helped to cut annual prostate cancer deaths in the United States by approximately 40 percent. Even with these cold, hard facts the ACS wants us to believe getting tested should be delayed and perhaps put off all together.

What is disturbing about the ACS announcement is that it comes on the eve of the first U.S. Congressional hearing on prostate cancer in 11 years. Approximately 4,000 men a week in the United States hear the words "you have prostate cancer." Nearly 28,000 men a year are killed by the disease in this country. Clearly, more research is needed to find the next generation PSA test or some other method that could detect the disease and give doctors better information about the aggressiveness of the cancer. Instead of calling on Congress to increase funding to fight prostate cancer, the ACS has decided to make a public stand just prior to the hearing that suggests all of the concern about prostate cancer is over blown. After all, they remind men in the new guidelines, prostate cancer can be slow moving. That's clearly code for "don't worry about it."

Try telling that to the men with advanced stages of the disease or the loved ones of men who passed away from prostate cancer because symptoms did not develop until after the disease had progressed too far for successful treatment. If I had followed the ACS advice, instead of getting tested at 47 years old, my prostate cancer would still be growing in my body and likely be on its way to killing me.

Prostate cancer in the US has the same social standing as breast cancer did 30 years ago. Women decided it was time to take a stand. It's time for men to tell the American Cancer Society and the US Congress to stop dragging their heels and start getting serious about fighting prostate cancer.

***

Rick Lyke is a prostate cancer survivor. After successful surgery in April 2008, he founded Pints for Prostates <www.pintsforprostates.org>, a campaign that uses the universal language of beer to reach men with an important health message. He serves on the Board of Directors of the Us TOO International Prostate Cancer Education and Support Network <www.ustoo.org>.

FINASTERIDE

(Continued from page 1)

from prostate cancer: a man has a less than 3% chance of dying from prostate cancer. For many men, potential adverse effects such as a reduction in libido, however mild, are experienced immediately and outweigh any reduction in what may seem like a rare and far-distant event.

These considerations may shift for a man who is informed that he is at high risk of prostate cancer. Furthermore, a formal economic analysis has found that finasteride is unlikely to be cost-effective for the entire male population, although it might be cost-effective in a subgroup of high-risk men. Researchers from MSKKC used the raw data from the PCPT to develop a model of chemopreventive treatment strategies – treat all men, treat no men, or treat a high-risk subgroup based on PSA level.

Of 9,058 men included in the analysis, 1,957 were diagnosed with prostate cancer during the 7-year study – 798 (18.3%) men in the finasteride group and 1,159 (24.7%) men in the placebo group. Baseline PSA, age, race, and family history were similar in finasteride and placebo groups. The results of this analysis indicate that treating high risk individuals (those with PSA >1.3 ng/mL) with finasteride would be unlikely to prevent all prostate cancers detectable at biopsy. It will only prevent, or delay the detection of clinically significant disease, i.e., a disease detected based on a rising PSA level, or an abnormal prostate exam. By contrast, to prevent all biopsy proven prostate cancer, all men needed to be treated, regardless of their baseline PSA risk category.

Accordingly, the interpretation of these results, whether finasteride should be used as a chemopreventive for all men or for just a higher risk subgroup, depends on the relative clinical significance of cancers found during a random biopsy.

One view is that such cancers are no less clinically relevant than those found following an elevated PSA or abnormal prostate digital rectal exami-

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DOC MOYAD'S WHAT WORKS & WHAT IS WORTHLESS COLUMN, ALSO KNOWN AS "NO BOGUS SCIENCE" COLUMN

"Weight loss supplements are a problem so be careful and pick the ones that are heart healthy – Part 2 of a semi-exciting 2 part series!"

Mark A. Moyad, MD, MPH,
University of Michigan Medical Center, Department of Urology

Editors' note: In the spirit of information sharing, we have invited certain physicians and others to provide comments and opinions for Us TOO's *HotSheet.* It is our desire to enrich the content of the *HotSheet* to empower the reader. Each piece contains the opinions and thoughts of its author and does not necessarily reflect those of Us TOO International.

Bottom Line: Most effective weight loss supplements have worked as stimulants that also raise heart rates and blood pressure, & cause liver injury (ouch!). Never take a weight loss supplement that is NOT heart healthy. My two favorite heart healthy supplements are fiber (mostly from cereal, fruit, veggies, beans…) and fish oil.

Fiber is your friend! Let me repeat this "Fiber is your friend!" Fish oil is your friend! Let me repeat this "Fish oil is your friend!" Since we already discussed fish oil in the last newsletter, there is no reason to swim back upstream (pun intended as always) and revisit this subject. Therefore, I want to provide a quick A to Z summary of what clinical research has demonstrated over the past few years with a daily intake of about 30 grams of fiber per day: only a reduction in acid reflux, blood glucose, blood pressure, cholesterol, constipation, diverticulitis, hemorrhoids, PSA, weight and waist size…blah, blah, blah.

Can you imagine all these benefits?! If the benefits of fiber could be put into a pill it would win a Nobel Prize! However, you do not really need most fiber pills, wafers, crackers, or even powders! (Ouch, there goes my chance of being in a fiber commercial!) All you need to do is invest in a box of All-Bran Buds that cost about 5 bucks a box and ALL YOU NEED IS ONE-THIRD OF A CUP A DAY!!! WHAT? THAT SEEMS CRAZY!!!

One-third cup is even smaller than a portion of food that you would feed a newborn puppy! People think they need to eat a bowl of All-Bran but they do not! One-third cup will give you almost 15 grams of fiber and mostly in the insoluble form so you will not be so gassy! If you add a little fruit, flaxseed (not the pill or oil but the seed or powder) or even put that one third a cup in your oatmeal-WHAMMO (and I do not mean the Frisbee company)! That is it and you are virtually done with your fiber requirement before you leave the door in the morning! Not bad at all.

Fiber sends a message to the brain that you are feeling full and it delays the movement and absorption of other foods and beverages and this allows your body to recognize faster when you have simply had enough. It is not unusual in many parts of the world, including areas of Japan, to eat something with fiber before big meals of the day. This helps to control the portion size of the meal itself. Also, fiber is not absorbed so it does not contribute in general to your calorie count.

The bottom line is that everyone is focusing on the magic pill for weight loss when all along the safest and most effective option is heart healthy and prostate healthy and is dirt-cheap!

In one of the largest fiber studies to be completed in the past year that was just released and showed weight and waist loss benefits, let me quote the conclusion of the large study:

"Our finding may support a beneficial role of higher intake of dietary fiber, especially cereal fiber, in prevention of body-weight and waist circumference gain."

Hey, didn't I just say that in the column?! Man, I love exclamation points! They make me feel as powerful as Tom Kirk at an advocacy event (that is pretty powerful my friends)!

Reference

Du H, van der A DL, Boshuizen HC, et al. Am J Clin Nutr 91: 329-36, 2009

J&J DRUG HELPS IN LAST-DITCH PROSTATE CANCER FIGHT

Johnson & Johnson's experimental drug abiraterone can help men with advanced prostate cancer who have run out of standard treatments options, according to results of a mid-stage clinical trial. The drug, which J&J took on after buying Cougar Biotechnology for about $970 million last year, has previously shown good results in men who did not receive chemotherapy.

The latest Phase II study tested it in patients after treatment with both hormone therapy and Sanofi-Aventis's Taxotere, or docetaxel, the only currently approved chemotherapy to show benefit in late-stage prostate cancer.

British researchers said that about half of the men given the drug experienced a substantial reduction in levels of prostate specific antigen (PSA) in their blood, the standard measure of prostate cancer activity. Three-quarters also had a drop in the number of circulating tumor cells, another measurement linked to increased survival rates, and five of the 47 patients were still taking the drug and getting benefit three years after the trial started.

Abiraterone, which is now in final-stage Phase III testing, was licensed by Cougar in 2004 from BTG and the British biotechnology company will enjoy a royalty on sales if it is a commercial success. Consensus forecasts suggest the drug will generate worldwide sales of $231 million in 2013, according to Thomson Pharma.

"Docetaxel is an important drug but it extends life for an average of just two to three months, so there is a desperate need to improve treatment options for late-stage prostate cancer patients," said chief investigator Dr Johann de Bono of Britain's Institute of Cancer Research and Royal Marsden Hospital. "In this trial, abiraterone shrank or stabilized men's cancers for an average of almost six months, which is a very impressive result."

The findings were release online ahead of publication in the *Journal of Clinical Oncology.*

Reuters UK, 16 February 2010

DOCTORCHODAK'S BOTTOM LINE

Editors' note: In the spirit of information sharing, we have invited certain physicians and others to provide comments and opinions for Us TOO's *HotSheet.* It is our desire to enrich the content of the *HotSheet* to empower the reader. Each piece contains the opinions and thoughts of its author and is not necessarily those of Us TOO International.

Two articles in this month's *HotSheet* summarize potentially new treatments for men with advanced prostate cancer. One looks at the effect of a low dose patch containing nitroglycerin, the same medicine used to treat angina, in men with a rising PSA after radiation or radical prostatectomy. The authors found that this drug prolonged the PSA doubling time, and in some men it actually caused a decline in the PSA. Although the study is very preliminary, the results certainly support further investigation.

The second new treatment is further along in its research process. The drug is called abiraterone acetate and it works by interfering with normal hormone production even after conventional hormone therapy has failed. It is now in the final phase of clinical testing in men who have progressive disease but are not ready for or they decided against receiving standard chemotherapy. If the results are positive, it could be available in a few years.

The Bottom Line: It is exciting to see real progress forthcoming for treating men who develop recurrent or progressive disease. Hopefully, future studies will be able to clearly prove that these treatments are worthwhile.

There is important information regarding minimally invasive radical prostatectomy and how it compares to open prostatectomy. Increasingly throughout the US, robotic surgery is heavily marketed as being better and safer than other surgical approaches. Unfortunately, no valid studies support this claim. The study cited here included Medicare patients treated throughout the US. It found that the overall complication rates were similar with a small difference in urethral strictures and on average one less day in the hospital with the minimally invasive approach. But so far there is no evidence for better urinary control, sexual function or cancer control. The most important message is that the complication rates are primarily affected by the surgeon's experience; those doing less than 30 per year had a significantly higher complication rate. This study found that more than half of the operations were performed by surgeons who did fewer than 5 per year on Medicare patients. This has important implications for men who decide that surgery is right for them.

The Bottom Line: Choose your surgeon rather than the type of surgery and don't be afraid to ask your surgeon how many he/she does per year and their specific complication rates.

The study about external radiation also has important implications for men who choose to be treated this way. This was a randomized trial comparing a higher dose of radiation to the dose that had been used for many years. The extra radiation was given using Proton therapy. The higher dose group had a lower local recurrence rate and a lower biochemical failure rate. However, after almost ten years, the survival was the same for men with low or intermediate risk disease. An important editorial accompanied the article <http://jco.ascopubs.org/cgi/reprint/28/7/1087> which makes several points. First, it questioned whether the best dose for men with low risk prostate cancer may be none at all given the small chance of dying from the disease. And second, although the men receiving the extra radiation dose were treated using Proton Beam rather than traditional photon beam radiation, this study in no way demonstrates a benefit of Proton beam over conventional radiation.

The Bottom Line: Patients who want to minimize their chance for a PSA recurrence should ask their radiotherapist if they will be using a higher dose of radiation, however, men with low risk disease who are over 65 should make sure they discuss the relative merits of radiation compared to active surveillance. We still need appropriate studies to know how Proton Beam radiation compares to other types of radiation before any claims can be made.

For friends and relatives of men who have been diagnosed with prostate cancer, they should be aware of the latest results from preventing the disease using finasteride; yes it reduces the risk of being diagnosed with prostate cancer by nearly 25%. However, it helps only 6 of 100 who take it and it is unclear if those cancers would have needed treatment had they not been prevented. This article is a good summary of the pros and cons of taking it.

The Bottom Line: For those looking to reduce prostate cancer risk, they can take daily finasteride until they reach an age where it is less of a concern, but they should realize the odds of benefit are small.

AMERICA'S PROSTATE CANCER ORGANIZATIONS OFFER POINTERS TO HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

"Eleven different US-based, patient-focused, prostate cancer education and advocacy organizations came together to offer Congressman Ed Towns and the committee our shared perspective on the critical priorities that will change the impact of prostate cancer on the lives of Americans and their families," stated Scott Williams of the Men's Health Network on behalf of America's Prostate Cancer Organizations.

"This shared perspective, provided on behalf of millions of American men and their families, clearly shows the importance of reform to address these issues," commented Thomas Farrington of the Prostate Health Education Network.

The full text of the testimony is available at <http://www.ustoo.org/UsTOOAdvocacyAlertV9.asp> and will also be published in the May *HotSheet*.

NITROGLYCERIN

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Results of the study, conducted by Queen's University researchers Robert Siemens, Jeremy Heaton, Michael Adams, Jun Kawakami and Charles Graham, appeared in a recent issue of the journal *Urology*.

Research into the use of nitroglycerin and similar compounds for the treatment of cancer by Drs. Adams, Graham and Heaton has resulted in the issue of 10 patents worldwide. PARTEQ Innovations, the technology transfer office of Queen's, has licensed some of this intellectual property to Nometics Inc., a Queen's spin-off company, which is developing products and therapies based on this and related research.

"This peer-reviewed research is our first clear clinical evidence that low-dose nitric oxide therapy offers prostate cancer patients a new non-invasive treatment option," says Robert Bender, CEO of Nometics. "It is our intention to start broader clinical trials in 2010 to confirm and expand these results."

ScienceDaily, 11 February 2010

ASK DR. MYERS

(Continued from page 8)

common causes of acute liver failure in the US and much of Europe. This drug becomes more dangerous if other treatments lessen the ability of the liver to defend itself.

Of the cancer drugs I use, ketoconazole is my biggest concern. At clinically used doses, ketoconazole can already cause mild to moderate liver injury. Ketoconazole is often used in advanced, hormone-refractory prostate cancer, a situation in which acetaminophen may be used for pain relief. The pure antiandrogens bicalutamide (Casodex®), nilutamide (Nilandron®) and flutamide (Eulexin®), can all cause liver damage, but this is less of a problem than it is with ketoconazole.

As a result, acetaminophen should be used with caution if you are on any of these drugs. Excessive alcohol intake has also been reported to increase the risk of acetaminophen-induced liver damage. I particularly worry about patients on ketoconazole or one of the antiandrogens who have a drinking bout and take acetaminophen for a hangover. It is easy to warn patients about Tylenol, but acetaminophen is also found in many cold medications.

FINASTERIDE

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nation. In this view, an important proportion of these cancers would grow and cause symptoms, even if they were not detected by usual screening procedures during the course of the study. An alternative view is that few of these cancers are clinically relevant, that is, if a cancer is not large enough to be found by screening, it is unlikely to become apparent during a man's lifetime in the absence of screening. There are several lines of evidence in favor of this second point of view.

The harms of finasteride are limited to a small reduction in sexual function. After 6 months of treatment, patients taking finasteride scored 3.2 points lower than controls from a mean close to 50 on a 100-point sexual functioning scale; this difference was slightly attenuated over time

In conclusion, the study suggest that the decision of who should receive finasteride to prevent prostate cancer, is determined based on the discussions between physicians and their patients. population of eligible age.

CancerWebMED, 18 February 2010

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