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Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

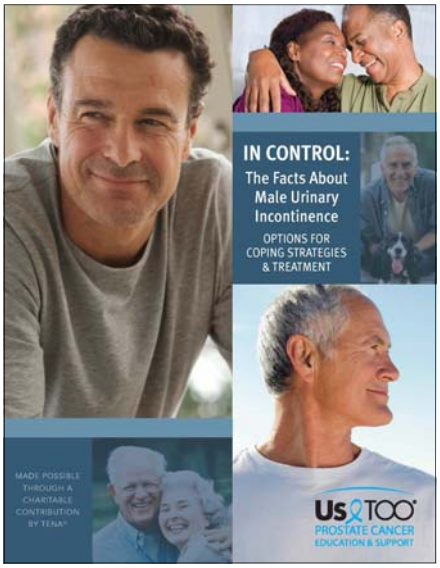
HOTSHEET

August 2009

New Urinary Continence Brochure Now Available

While up to 3.5 million men in the United States are affected by urinary incontinence, research shows they're the last to tell you. Men are far less likely than women to talk about their health, and when it comes to incontinence, the bathroom door is firmly closed on the discussion. Talking about urinary incontinence has long been considered taboo, but the condition is experienced by approximately one in ten men during their lifetime and is a common side effect of prostate cancer treatment.

To help reach men and their loved ones affected by this condition, SCA Personal Care North America, which markets bladder control products and services under the TENA® brand (formerly known as Serenity®), has collaborated with Us TOO International to develop educational resources including a male urinary incontinence brochure that will be made widely available free of charge.



The brochure, entitled IN CONTROL: The Facts About Male Urinary Incontinence - OPTIONS FOR COPING STRATEGIES & TREATMENT provides information and options to help men who have had prostate cancer and experience bladder control issues feel more in control of their condition.

"Men recovering from prostate cancer go through a lot both physically and mentally. Once they get past the struggle with diagnosis and treatments they can be left with serious post-treatment issues like urinary incontinence, which can leave them feeling confused and embarrassed," said Tom Kirk, President & CEO, Us TOO International. "Our goal is to provide men with valuable resources that help them manage the emotional and physical symptoms of urinary incontinence."

In Control is now available in two formats, in print and downloadable from Us TOO's website, <www.ustoo.org/freematerials>.

Prostate Cancer Patients Should Not Take Selenium Supplements

"If you already have prostate cancer, it may be a bad thing to take selenium," says the senior author of a new study published online 15 June 2009 in the *Journal of Clinical Oncology*.

In the study, Philip Kantoff, MD, director of genitourinary oncology at the Dana-Farber Cancer Institute in Boston and colleagues at the University of California, San Francisco, found that having a high level of selenium in the blood was associated with a slightly elevated risk of aggressive prostate cancer. But the risk was particularly elevated in men who also had a certain variant of the gene coding for manganese superoxide dismutase (SOD2). For these men, who made up 75% of the study population, having "high selenium levels might increase the likelihood of having worse characteristics," the researchers concluded.

The study involved 489 patients who had been diagnosed with prostate cancer at the Dana Farber Center between 1994 and 2001. These men had a mean age of 62 years and mean PSA level of 6.0 ng/mL. More than half had good-risk disease, while about a third had intermediate-risk disease, the research-

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PROSTATE CANCER TEST IMPROVES PREDICTION OF DISEASE COURSE

A new prostate cancer risk assessment test provides a better way of gauging long-term risks and pinpointing high risk cases. The findings, published in the 9 June 2009 online edition of the *Journal of the National Cancer Institute*, showed that the test proved accurate in predicting bone metastasis, prostate cancer-specific mortality, and all-cause mortality when localized prostate cancer is first diagnosed.

"This test should help physicians and their patients predict the likely course of the individual's disease," said lead investigator Matthew R. Cooperberg, MD, Department of Urology, University of California at San Francisco (UCSF) and the UCSF Helen Diller Family Comprehensive Cancer Center, San Francisco, CA. The test is known as the UCSF Cancer of the Prostate Risk Assessment, or CAPRA.

"In this study, we looked at the CAPRA score's ability to predict mortality across multiple forms of treatment. It should help patients and clinicians decide which tumors need to be treated, and how aggressively. We also hope that in the research setting it can serve as a well-validated and consistent means of classifying men into low, intermediate and high risk groups." More than 100 risk assessment tests have been developed in recent years, but most are unable to predict long-term outcomes and are applicable to just 1 form of treatment, rather than providing information relevant to multiple treatment modalities.

Because of these limitations, the researchers developed the CAPRA test. It calculates patient risk through 5 factors: age at diagnosis, Gleason score, prostate-specific antigen (PSA) score, percentage of biopsy scores that test positive for cancer, and clinical tumor stage based on digital exam of the prostate and/or ultrasound.

"The goal of risk assessment is to find the patients at high risk of mortality and treat them aggressively, and for others to guide their treatment or surveillance plan accordingly," said Dr. Cooperberg.

(Continued on page 8)

PREDICTING THE RETURN OF PROSTATE CANCER: NEW STUDY BETTERS THE ODDS OF SUCCESS

Cancer experts at Johns Hopkins say a study that tracked prostate cancer patients for a median of 8 years shows that a three-way combination of measurements has the best chance yet of predicting disease metastasis. Findings from the study were presented at the 2009 ASCO meeting and investigators suggest this may help determine which patients may benefit from additional therapy when PSA levels rise after radical prostatectomy (RP).

After reviewing the records of 774 men whose PSA rose after RP, the researchers found that Gleason score and two measurements for PSA were the strongest risk factors for prostate cancer metastasis. Men with Gleason scores in the highest range, between 8 and 10, were twice as likely to develop metastatic cancer. In men whose PSA

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US TOO SEEKS BOARD MEMBER APPLICATIONS

Us TOO is pleased to announce the annual public call for nominations to the Us TOO International Board of Directors. The Board Membership Committee, chaired by Carl Frankel, will review and evaluate nominees and submit recommendations to the full Board for approval at its December 2009 Board meeting.

Selection criteria includes items such as the candidate's relationship to Us TOO's purpose, its membership criteria ("…any man diagnosed with prostate cancer, a member of such a man's family or significant other, or any person involved in or interested in support or treatment of any such patients…"), familiarity with an Us TOO chapter, ability to think globally, skills or experience deemed beneficial to the work of Us TOO and commitment to Us TOO's purpose and mission.

Letters of nomination with a vita or resume should be sent by August 31, 2009 to Thomas Kirk, President/CEO, Us TOO International, 5003 Fairview Avenue, Downers Grove, IL 60515 or e-mail <tom@ustoo.org>.

PROSTATE CANCER SCREENING: A QUESTION OF COMMON SENSE

Professor Dr. Louis Denis

The following article is reprinted from the July/August 2009 issue of Cancer World with permission by the author. Dr. Denis is a past president of the EORTC and co-coordinator of the European Randomized Study of Screening for Prostate Cancer. He also is a core leader of Us TOO-Belgium.

First results of randomised clinical screening trials are traditionally met with a barrage of comments by opinionated observers, and the back-to-back publication in the March 26 issue of the New England Journal of Medicine on the mortality results of two major PSA screening trials – one European, one American – was no exception. Not only did it reignite the existing controversy but it brought utter confusion to the professional and public media.

In the case of the European Randomized Study of Screening for Prostate Cancer (ERSPC), the investigators had felt obliged to publish mortality results after the monitoring committee confirmed a clear 20% reduction in prostate cancer mortality in 162,000 participants. Whether by chance or design, the board of the US Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial then decided to publish their results, on the grounds that they were concerned about the lack of mortality benefit and emerging evidence of net harm.

No wonder many people felt confused. Careful reading of the two reports, however, shows they are not as contradictory as they might seem, and both point to a common sense approach.

The European study was always likely to show any mortality benefit at an earlier time point, because it is a much larger study, and therefore has greater statistical power. Furthermore, high levels of prostate screening in the general US population means that many in the screening arm will already have been screened before joining the trial, while many in the control arm will have undergone screening during the trial, thus reducing the difference between the two arms. In contrast, the European study shows all conditions of a successful screening trial: many more cancers are diagnosed in the screening arm with the lower grade and stage needed to show mortality benefit.

The two data sets offer complementary insights into the possible harm resulting from participation in PSA screening trials, with both studies pointing to overdiagnosis and overtreatment as the most important adverse effect. No precise figures are shown, but the European study has been reporting on the problem for six years. Many centers are now collaborating in an initiative using 'active surveillance' as a way to avoid early invasive treatment (see <www.prias-project.org>).

Before health authorities can make informed policy on population PSA screening, longer follow-up is needed to provide information on the expected increase in mortality benefit as well as on quality-of-life considerations and cost-effectiveness.

In the meantime, doctors and their patients should make intelligent use of what we already know, as the basis to reach shared decisions. More research on new specific markers to diagnose aggressive forms of prostate cancer remains a clinical priority.

EVEN WITH UNDETECTABLE PSA, MEN WITH LOCALLY ADVANCED PROSTATE CANCER BENEFIT FROM ADJUVANT RADIATION

There is now additional evidence that supports the use of adjuvant radiation (ART) in men with prostate cancer who have undergone radical prostatectomy (RP) and have pathologic stage T3 (pT3) disease, according to an editorial published in the 209 June 2009 issue of the *Journal of Clinical Oncology* (Vol.27, pp. 2924-30). "A debate has raged for decades over the utility of ART in treating these men," write Dr. Thompson and his coauthors. The debate has been reopened with the publication of a new study from Germany in the same issue of the Journal, which prompted the editorial.

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PROSTATE SHRINKAGE MAY REVEAL HIGH-GRADE CANCER

Treatment-induced prostate shrinkage likely unmasked high-grade cancers, resulting in a detection bias in the finasteride (Proscar®/Propecia®) arm of the Prostate Cancer Prevention Trial (PCPT), data from a large patient series suggest.

The value of PSA as a marker for prostate cancer declined steadily as prostate volume increased. A similar inverse relationship existed for high-grade cancer, Christopher S. Elliott, MD, of Stanford University, and colleagues reported in the 15 July issue of Clinical Cancer Research (Vol. 15, pp. 4694-9, 2009).

"Decreases in prostate volume over time and the resultant change in prostate-specific antigen performance characteristics may have contributed a bias toward the detection of high-grade disease in the finasteride arm of the Prostate Cancer Prevention Trial," the authors concluded.

The observations could explain why the increased risk of high-grade cancer in the finasteride arm was limited to the subgroup of men who had symptom-driven biopsies during the trial, they added. The findings also are consistent with those from analyses that PCPT investigators have performed in the six years since the trial ended.

The PCPT involved 19,000 healthy men who were randomized to finasteride or placebo for seven years. The principal finding was a 25% reduction in prostate cancer incidence in the finasteride arm. However, the beneficial effect has been overshadowed by the finding that finasteride-treated men had a small but statistically significant increase in the rate of high-grade cancer compared with the placebo group.

Closer examination of the PCPT data revealed inconsistencies in the occurrence of high-grade cancer. Specifically, the increase was limited to men who had "for-cause" biopsies, triggered by an abnormal digital rectal exam (DRE) or a rise in PSA. End-of-study biopsies showed an almost-identical incidence of high-grade cancer in the two treatment arms. Prostate

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SELENIUM MAY BE BAD

(Continued from page 1)

ers comment. The team examined banked blood samples for selenium levels and also for genomic DNA, in particular genotyping for SOD2 polymorphism: 25% of men were found to carry the A form of the gene, and 75% carried the V form of the gene.

Dr. Kantoff and colleagues found that having higher vs. lower selenium blood levels was associated with a slightly increased likelihood of presenting with aggressive disease (relative risk, 1.35). The mean selenium level (121 ng/mL) in this patient population was similar to that reported in several other studies. This study also found no effect of SOD2 genotype on disease aggressiveness, although this effect was reported previously both by this team and others.

However, there was evidence of an interaction between the SOD2 genotype and selenium levels. Among men with the AA genotype, higher selenium levels were associated with a 40% reduced risk of presenting with aggressive disease (relative risk, 0.60), while among men with the V allele (either VV or VA genotype), higher selenium levels were associated with an almost doubling of the risk of aggressive disease (relative risk, 1.82; P = 0.007 for the interaction).

"These data suggest that the relationship between circulating selenium levels at diagnosis and the prognostic risk of prostate cancer is modified by the SOD2 genotype and indicate caution against broad use of selenium supplementation for men with prostate cancer," the authors conclude.

The results were unexpected, and they are the first to raise concern about potentially harmful consequences of taking supplemental selenium. "It is possible that selenium helps some and may harm others," Dr. Kantoff commented. "Genetic studies will help sort this out. Until then, I would not advise taking selenium supplements," he said.

Dr. Kantoff added that it is now "essential" to go back and genotype the men in the SELECT trial. "There may be some people who benefit and some who do not or are even harmed."

Medscape Medical News, 1 July 2009

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

"An LDL cholesterol <70 mg/dL and an hs-CRP <1 mg/L (both cheap blood tests) should be the new gold standard of health for all individuals"

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

Bottom Line: A cholesterol blood test is important, but it is better if an hs-CRP blood test is also done at the exact same time.

Statins not only reduce cholesterol, but also tend to reduce blood markers or levels of inflammation such as hs-CRP in the human body, which may play a role in the risk and prognosis of heart disease and cancer. The JUPITER trial[1] was one of the most important cardiovascular prevention trials in medicine to demonstrate that otherwise healthy individuals that started the clinical trial with a normal cholesterol (LDL of 100 mg/dL) and elevated hs-CRP levels (above 2 mg/L) could reduce their risk of a future cardiovascular event (CVE) by taking a low-dose statin drug (20 mg of rosuvastatin, also known as Crestor®).

The JUPITER trial was stopped only 1.9 years into the 5-year study because of the dramatic and rapid positive results. However, researchers still had to determine if there was a continuous reduction in CVEs with greater reductions in LDL, and hs-CRP levels in the JUPITER trial. A total of 15,548 healthy men and women that participated in the randomized, double-blind, placebo controlled JUPITER trial were analyzed based on their LDL and hs-CRP levels. A CVE in this study consisted of one of the following: non-fatal myocardial infarction, non-fatal stroke, unstable angina, arterial revascularization (surgical procedure), or cardiovascular death.

The average age of the participants was 65 years old. Individuals having the LDL and hs-CRP levels listed in the table to the right had the following rates of CVE events when taking this statin compared to placebo:

The 20 mg statin reduced the LDL cholesterol by 50% and hs-CRP by 37% compared to placebo. Therefore, a reduction in both LDL and hs-CRP are the best indicators of a potential positive impact with a statin drug in healthy individuals.

LDL (mg/dL)	Hs-CRP (mg/L)	CVE vs. placebo
>70	>1	↓ 9%
>70	<1	↓ 35%
<70	>1	↓ 50%
<70	<1	↓ 79%

This study is nothing less than amazing in terms of the potential clinical impact of the findings. I get tired of so called "experts" telling the public that an LDL of 130 or 160 or less is acceptable and hs-CRP blood test needs more evidence before it is offered to patients. We need to remember that the alternative consequence (aka death) of not being aggressive in terms of education and intervention is completely unacceptable.

However, I am not suggesting that everyone has to achieve these exact low numbers regardless of cost and side effects, but at least they should be made aware of or have the right to know what the ultimate goal is today for any individual. This is similar to what we do now with waist size, BMI, blood pressure, etc., so why not with these blood tests?! If someone can achieve these numbers with moderate lifestyle changes and without medication that is great, but if they cannot they should be offered medication that can help them get as close to this goal as possible.

I also believe that these are the numbers that will be associated with a potential reduction in the risk or risk of progression with certain forms of cancer. I hope I am right, but if not, who cares because at least it will still help to reduce the number 1 cause of death over the last 109 years in the US in men and women (aka cardiovascular disease) .

Reference

1. *Ridker PM, Danielson E, Fonseca FA, et al. Lancet 373:1175-82, 2009*

PREDICTING PSA RETURN

(Continued from page 2)

became detectable within 3 years after RP, cancer was more than three times more likely to metastasize. Finally, men whose PSA doubled within three months were more than 20 times more likely to develop metastatic cancer than men whose PSA look longer than 15 months to double.

An increase in PSA occurs in approximately 20 percent to 30 percent of men after surgery to remove the cancerous prostate, says Emmanuel Antonarakis, MD, Johns Hopkins Kimmel Cancer Center investigator. In these patients, the cancer is rarely detectable on imaging scans. When faced with the likelihood that their cancer has spread, many men opt to undergo androgen deprivation treatment (ADT), which can cause side effects mimicking those experienced by menopausal women.

"There is much debate on whether to prescribe immediate treatment for a man whose PSA begins to rise after he has had prostate cancer surgery, or to delay it," says Antonarakis. "Studies suggest that most men live the same length of time overall whether they receive therapy at the first sign of a rising PSA or wait until the cancer has spread to other sites."

Besides immediate ADT, men with a rising PSA can consider other options, such as intermittent ADT, expectant management or participation in clinical trials for experimental therapies.

ScienceDaily, 3 July 2009

DENOSUMAB DEMONSTRATES SUPERIORITY OVER ZOMETA® IN PIVOTAL PHASE 3 HEAD-TO-HEAD TRIAL IN BREAST CANCER PATIENTS WITH BONE METASTASES

Amgen announced that a pivotal, Phase 3, head-to-head trial evaluating denosumab versus Zometa® (zoledronic acid) in the treatment of bone metastases in 2,049 patients with advanced breast cancer met its primary and secondary endpoints and demonstrated superior efficacy compared to Zometa.

This was an international, randomized, double-blind study wherein enrolled patients were randomized in a one-to-one ratio to receive either 120 mg of denosumab subcutaneously every four weeks or Zometa administered intravenously at a dose of 4 mg single, 15 minute infusion every four weeks as per the labeled use.

Bone metastases, the spread of tumors to the bone, are a serious concern for advanced breast cancer patients, with incidence rates as high as 75 percent. When cancer spreads to the bone, the growing cancer cells weaken and destroy the bone around the tumor. This damage can result in a number of serious bone complications, collectively called skeletal related events (SREs).

Superiority was demonstrated for both delaying the time to the first on-study SRE (fracture, radiation to bone, surgery to bone, or spinal cord compression) (hazard ratio 0.82, 95 percent CI: 0.71, 0.95), and delaying the time to the first-and-subsequent SREs (hazard ratio 0.77, 95 percent CI: 0.66, 0.89). Both results were statistically significant.

Overall, the incidence of adverse events and serious adverse events was consistent with what has previously been reported for these two agents. Of note, osteonecrosis of the jaw (ONJ) was seen infrequently in both treatment groups. There was no statistically significant difference in the rate of ONJ between the two treatment arms. Infectious adverse events were balanced between the two treatment arms, as was overall survival and the time to cancer progression.

"We are extremely pleased with the outcome of this important study, which shows that denosumab can reduce or delay the serious complications of bone metastases in breast cancer patients better than the current standard of care, and with a favorable benefit/risk profile," said Roger M. Perlmutter, MD, PhD, executive vice president of Research and Development at Amgen. "These results underscore the importance of the RANK Ligand pathway in bone disease, and offer the promise of improved care for patients with advanced breast cancer."

Full efficacy and safety data will be submitted for presentation at an upcoming medical meeting in the second half of this year.

Amgen News Release, 7 July 2009

PCRI CONFERENCE
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US COMPARATIVE RESEARCH PROPOSAL INCLUDES MULTIPLE ONCOLOGY STUDIES

A new report from the Institute of Medicine (IOM) proposes an initial 100 health topics, including a variety of oncology-related subjects, as priorities in comparative-effectiveness research in the US. Some of the proposed studies, including a comparison of the management of localized prostate cancer, include cost as a consideration.

The proposed comparative research is an outgrowth of the American Recovery and Reinvestment Act of 2009, which is federal legislation that called upon the IOM to draft the report. The report provides independent guidance to Congress and the secretary of the US Department of Health and Human Services on how to spend $400 million on research to compare health services and approaches to care, according to a statement from the National Academy of Sciences, of which the IOM is a part.

Comparative-effectiveness research weighs the benefits and harms of various methods to prevent, diagnose, treat, or monitor clinical conditions to determine which work best for particular types of patients and in different settings and circumstances, according to the IOM report.

In the report, the 100 initial topics are listed by quartile, or groups of 25, with the first quartile considered the highest-priority group and the fourth quartile the lowest. However, the topics in each quartile are not ranked in any way by order of importance.

Among the oncology-related topics in the first quartile, and thus of paramount importance, are proposed studies that compare the effectiveness of:

- Management strategies for ductal carcinoma in situ (DCIS).
- Management strategies for localized prostate cancer (e.g., active surveillance, radical prostatectomy [conventional, robotic, and laparoscopic], and radiotherapy [conformal, brachytherapy, proton-beam, and intensity-modulated radiotherapy]) on survival, recurrence, adverse effects, quality of life, and costs.
- Imaging technologies in diagnosing, staging, and monitoring patients with cancer, including positron-emission tomography (PET), magnetic resonance imaging (MRI), and computed tomography (CT).
- Genetic and biomarker testing and usual care in preventing and treating breast, colorectal, prostate, lung, and ovarian cancer.
- Upper-endoscopy utilization and frequency for patients with gastroesophageal reflux disease on morbidity, quality of life, and diagnosis of esophageal adenocarcinoma.
- Interventions (such as community-based multilevel interventions, simple health education, usual care) to reduce health disparities in cancer and other conditions.

Oncology-related topics in the second quartile include proposed comparisons of the effectiveness of:

- Robotic assistance surgery and conventional surgery for common operations such as prostatectomy.
- Film-screen or digital mammography alone and mammography plus MRI in community practice-based screening for breast cancer in high-risk women of different ages, risk factors, and race or ethnicity.
- New screening technologies (such as fecal immunochemical tests and CT colonography) and usual care (fecal occult blood tests and colonoscopy) in preventing colorectal cancer.

Oncology-related topics in the third quartile include a proposed comparison of the effectiveness of:

- Different benefit design, utilization-management, and cost-sharing strategies in improving healthcare access and quality in patients with chronic diseases including cancer.

Oncology-related topics in the fourth quartile include proposed comparisons of the effectiveness of:

- Surgical resection, observation, or ablative techniques on disease-free

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PROSTATE SHRINKAGE

(Continued from page 3)

volume at the time of biopsy was 25% lower in the finasteride arm (25.5 cm^3 versus 33.6 cm^3), the authors noted.

Dr. Elliott and colleagues hypothesized that the increased rate of high-grade cancer in the finasteride arm resulted from the drug's volume-reducing effect on the prostate. The shrinkage could have improved PSA's performance characteristics for detecting prostate cancer.

To test their hypothesis, investigators retrospectively reviewed records on 1,304 men referred for an initial prostate biopsy due to a PSA value of 4 to 10 ng/mL or an abnormal digital rectal exam. The study group had a median age of 66, median prostate volume of 42.9 cm^3, and median PSA value of 5.5 ng/mL. Digital rectal exam was abnormal in 507 (38.9%).

The investigators calculated receiver-operator curves and positive predictive values for PSA, stratified by diagnosis and prostate volume. For detection of any cancer, the area under the curve (AUC) decreased from 0.758 to 0.520 as prostate volume increased from <30 cm^3 to >50 cm^3. For high-grade cancers, AUC decreased from 0.712 to 0.497 as organ volume increased.

A similar pattern emerged from calculations of positive predictive values. For a prostate volume <30 cm^3, the positive predictive value of a PSA of ≥4 ng/mL was 25%, declining to 17.3% for a prostate volume >50 cm^3. The differences increased for detection of high-grade cancer: 39% for a prostate volume <30 cm^3 versus 10.7% for a volume >50 cm^3.

Continued analysis of PCPT data has led to similar conclusions regarding the relationships among finasteride, prostate volume, and PSA performance characteristics for detection of prostate cancer, PCPT investigator Catherine Tangen, DrPH, of the Fred Hutchinson Cancer Research Center in Seattle, WA, said in a statement.

Collectively, the data suggest that men should be offered finasteride, if they and their physicians agree that chemoprevention might be beneficial, she added.

MedPage Today, 7 July 2009

THE DOCTORS NOTE – GERALD CHODAK, MD

What an interesting sequence of events. For years men have been told of the potential benefit of selenium and vitamin E for prostate cancer prevention and as part of overall treatment. Many swore by it and patients embraced it. Then along comes a government sponsored prospective randomized study showing it does not prevent prostate cancer. Now we have data from Boston suggesting (though not proving) that it actually might be bad for some men with prostate cancer. Although this story is still unfolding, there already is an important take-home message for men with this disease or those hoping to prevent it; DO NOT assume that supplements and other unconventional therapies are safe to take until someone shows they are not. As more studies are done, we find not only do the supplements not help, but there are real risks. At the very least, make sure to tell your physician what unprescribed medications you are taking so you can discuss it with him/her.

Other medications often taken without prescription are NSAIDs, Nonsteroidal Anti-inflammatory Drugs. Is it possible that they make the diagnosis of prostate cancer more difficult? A retrospective analysis from Tennessee makes this suggestion but there is much information absent from the study. The fact that the mean PSA level was lower in those on aspirin does not really prove that cancers will not be diagnosed. Most of the men whose PSA declined still had a PSA level still that would have warranted a biopsy. Furthermore, some men who do have a high PSA may actually be spared from an unnecessary biopsy because the elevation is from inflammation and that is helped by the NSAID. For now, men without a diagnosis of prostate cancer who are on one of these medications need not be alarmed.

For those who have been diagnosed, a critical question is how dangerous is that cancer? If low risk cancers could be identified, men could consider selecting active surveillance with greater reassurance. A study cited in this issue using the CAPRA score (Cancer of the Prostate Risk Assessment Score) suggests it could be a good tool for predicting risk. Unfortunately, the reliability of this score is still unclear and there are some shortcomings. First, the major weakness is that it is based on data collected in an uncontrolled manner and without validation that the information is accurate. Before embracing its use, the method should be subjected to rigorous testing in a more controlled manner. Until then, caution is recommended.

Another predictive tool is cited for those men who have undergone radical prostatectomy. A study from John's Hopkins provided additional data that reinforces the characteristics of dangerous tumors. Those men who had a rising PSA within 3 years of surgery or a PSA doubling time of less than three months carried a high risk of eventually dying from the disease. These men should consider a more aggressive approach while others with a longer delay until PSA recurrence or a slower doubling time can avoid the side effects of additional therapies and continue to be observed.

For those men who undergo radical prostatectomy and have extracapsular disease, another randomized study performed in Germany provides additional evidence that postoperative radiation for these men can reduce the risk for recurrence. Although this study does not report on survival and is therefore not conclusive, it is consistent with a US trial that showed a benefit even for men whose PSA was undetectable. The trade-off, however, is that only about 20% of men will benefit from the radiation at ten years meaning that men will have to weigh this level of benefit against the risk of over-treatment.

Lastly, one study not included in this issue is a recent publication of a randomized study comparing 6 months against 36 months of medical castration in men with extracapsular prostate cancer scheduled to receive external radiation. There have been a number of studies looking at this question with some physicians suggesting that less is better. This study reaffirms the need for longer duration of hormone therapy to reduce mortality. Six months of castration was inferior and patients should make sure to discuss this with their doctor.

A final note to encourage patients to visit <www.ProstateVideos.com> for the latest updates on prostate cancer in a video format that may provide useful information.

NSAIDS MAY AFFECT PSA LEVELS AND PROSTATE CANCER RISK

Nonsteroidal anti-inflammatory drugs (NSAIDs) may affect prostate cancer detection says a report in the *Journal of Urology* (Vol. 181, pp. 2064-70, 2009).

Dr. Jay H. Fowke of Vanderbilt University Medical Center, Nashville, TN and colleagues studied 1277 men who had diagnostic prostate biopsies. About 46% were receiving NSAIDs, with >95% of those taking aspirin.

Prostate volume was similar between aspirin users and non-users, but mean PSA levels were significantly lower in aspirin users (7.3 ng/mL) than in non-users (8.0 ng/mL). The association between PSA and aspirin use was significant in men with latent prostate cancer, marginal in those with high grade PIN, and nonsignificant in men with negative biopsies.

"This analysis, raises the concern that aspirin and other NSAIDs may lower PSA levels below the level of clinical suspicion without having any effect on prostate cancer development, and if that is true, use of these agents could be hampering our ability to detect early-stage prostate cancer through PSA screening." Dr. Fowke stated.

"Several prior studies reported anti-inflammatory drugs like NSAIDs were associated with lower prostate cancer risk," Dr. Fowke said. "Our data… could be consistent with a protective effect, because aspirin reduced PSA levels more among those men who were diagnosed with prostate cancer than among men with other prostate diseases."

Reuters Health, 23 June 2009

SNEAKERS@WORK DAY
Friday, 18 September 2009

<www.ustoo.org/sneakers@work

POST-RP ART BENEFICIAL

(Continued from page 3)

The German study, led by Thomas Wiegel, MD, from University Hospital Ulm, provides further evidence for benefit from RT. Among 265 men with undetectable PSA post-RP and pT3 disease, the 5-year biochemical progression-free survival was 72% in the group of men randomized to treatment with ART and 54% in the wait-and-see group.

"Our findings suggest positive margins, a PSA level more than 10 ng/mL before RP, or extracapsular extension without infiltration of the seminal vesicles to be predictors of an increased effect of ART," write Dr. Wiegel and colleagues. Positive margins were the strongest predictor of benefit (P = 0.00018).

In the editorial, Dr. Thompson and his coauthors are not as forceful, but state their case clearly: "We feel that clinicians cannot tell patients that waiting until a PSA becomes detectable using an ultrasensitive assay is just as good as undergoing ART. Such a statement would be based on faith, not data."

Medscape Medical News, 25 June 2009

CAPRA SCORE

(Continued from page 2)

The study looked at 10,627 men from the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE). A national disease registry launched by UCSF in 1995, it tracks prostate cancer patients at 40 primarily community-based urology practices across the US. The patients in the study had undergone radical prostatectomy, radiation therapy, androgen deprivation therapy or watchful waiting.

Nearly 3% (311) of the men developed bone metastases, 2.4% (251) died of prostate cancer, and 14.9% (1,582) died of other causes. The CAPRA score accurately predicted all 3 outcomes. The study determined that with each point increase in CAPRA score, the risk of death from prostate cancer increases 39%; with each 2-point increase in score, risk roughly doubles. The tool can predict risk up to 10 years.

"Given its high degree of accuracy and ease of calculation, the CAPRA score may prove an increasingly valuable tool for risk stratification in both the clinical practice and the research setting," wrote the study authors.

Doctor's Guide News, 15 June 2009

COMPARATIVE RESEARCH

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and overall survival, tumor recurrence, quality of life, and toxicity in patients with liver metastases.

- Hospital-based palliative care and usual care on patient-reported outcomes and cost.

The new report from the IOM with the 100 health topics is an important step in what will be an ongoing process, suggested 1 of the report cochairs.

"This report lays the foundation for an ongoing enterprise to provide the evidence that healthcare providers need to make better decisions and achieve better results," said the report cochair Sheldon Greenfield, MD, Donald Bren Professor of Medicine and executive director of the Health Policy Research Institute at the University of California, Irvine.

The report is available for purchase at <www.nap.edu/catalog.php?record_id=12648>.

Medscape Medical News, 7 July 2009

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