CALIFORNIA Prostate Cancer COALITION

"Fighting Prostate Cancer in California!"

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NEWS

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PRESIDENT'S MESSAGE

There have already been repercussions from the June 2012 US Preventive Services Task Force (USPSTF) "D" Recommendation against PSA testing in men who have no symptoms, regardless of family history or other risk. The number of men for whom primary care physicians are ordering a PSA test has been reported to have steeply declined (and who knows if they are even having an "informed" discussion with them about the test). In addition, urologists have reported a sharp decline in the number of men referred to them for diagnosis or follow-up. There are exceptions. Dr. Joseph Scherger on the Board of CPCC and an esteemed Family Practice physician, still obtains PSA's on his male patients of the appropriate age, and has offered to help CPCC in its quest to turn back the decline in testing. To the extent that new diagnostic tests can discern which patients have a greater risk of having significant, potentially fatal prostate cancer, we may be able to refer those patients to urologists while not referring others, thereby helping to refute the Task Force's worry about over-treatment.

CPCC held a successful Northern California Support Group Leaders' Workshop in San Francisco, CA in October, led by our CPCC Board Member Stan Rosenfeld. This is always a popular event since it allows support groups leaders to express their concerns and ask questions about how to handle various situations that come up during support group meetings. The National Alliance of State Prostate Cancer Coalitions (NASPCC) held its 7th Annual Meeting in October in Washington DC. The substantive content was superb. Several biomarker and diagnostics companies presented information about their new tests, and support came from companies such as Genomic Health, Iris Diagnostics, Ventana/ Roche and Myriad Genetics, among others. We also heard about "Transparency and the Affordable Health Care Act" and from a Congressional Aide talking about legislative efforts to reform the USPSTF, a re-modeling which would include mandating the USPSTF to consult with experts in the field, as well as with advocates, when developing new Guidelines.

I will be traveling to Washington DC to attend the Prostate Cancer Roundtable, of which NASPCC is a member; the Society of Urologic Oncology Winter Meeting and the NCCN Advocacy Meeting later this month. I will also be attending the European Multi-Disciplinary Urologic Cancers Meeting next week as well. I will report back on any new guidelines**,** tests and products I learn about.

Wishing you all a happy, healthy holiday season and a healthy new year.

Respectfully submitted, Merel Grey Nissenberg, Esq.

PSA SCREENING RATE DROPS AFTER MAJOR TRIAL RESULTS RELEASED

The number of men screened for prostate cancer has sharply declined since the publication of a major trial showing no improvement of mortality rates from screening with the PSA test. Reasons for screening have also shifted, according to research presented at the American Public Health Association (APHA) 140th Annual Meeting.

Researchers evaluated data gathered from participants who received prostate cancer screenings at 41 cancer screening sites across the country as part of Prostate Cancer Awareness Week campaigns in 2008 and 2011. These years were chosen because they represent those before and after the publication of the highly publicized US Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial, which found no statistically significant effect of PSA-based screening on prostate cancer mortality after 10 years.

For the study, the researchers analyzed data on social and health-related issues obtained in self-reported questionnaires given at the screenings. The findings showed a decline in screenings from just over 8,000 in 2008 to just over 6,000 in 2011, which was a bit of a surprise, said lead author Wendy L. Poage, MHA, of the Prostate Conditions Education Council.

"Our findings did indicate a reduction in participation in screening, which we expected," she said. "However, we were surprised by the magnitude of this, as it is a 25% reduction in participation between 2008 and 2011 in this longitudinal study group." Poage added,

"We didn't find any real difference in terms of who participated in 2008 and 2011 based on age, so it was pretty consistent between the 2 years," which she said is good . "We would like to see an increase in the number of 41- to 55-year-olds receiving screening," she added. "I think that age group is where we can do the most good."

The data also showed some interesting shifts in the reasons the men stated for receiving the screenings. In 2008, for instance, 7.8% of respondents said they received the screening because they believed they were at high risk, compared with just 3.2% in 2011. "There was a

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POSTOP RADIATION SLOWS PSA RISE IN HIGH-RISK PROSTATE CANCER

Men with high-risk prostate cancer had a significantly lower risk of biochemical relapse (BCR) when treated with adjuvant radiation therapy (ART) after radical prostatectomy (RP), results of a large randomized trial showed. After a median follow-up of almost 11 years, men who received RT after RP had a BCR rate of 39.4% compared with 61.8% in men randomized to a wait-and-see policy after RP. However, the reduced risk of BCR did not translate into a survival benefit as reported online in *The Lancet*.

For organ-confined prostate cancer, RP achieves good long-term local control. However, extracapsular extension or seminal vesicle invasion is associated with a risk of local failure as high as 50%, the authors noted in their introduction. Higher Gleason score, higher baseline PSA level, and positive surgical margins, along with seminal vesicle invasion, have proven to be independent predictors of biochemical progression-free survival (bPFS).

Principal eligibility criteria for EORTC 22911 included age 75 or younger, WHO performance status 0 or 1, and previously untreated stage cT0-3 cN0 M0 prostate cancer (pathologic stage pT2-3 N0) with at least one high-risk feature: extracapsular extension, positive surgical margins, or seminal vesicle invasion.

The analysis included 1,005 patients, all of whom underwent RP, followed by randomization to immediate RT or active surveillance (AS) and RT delayed until BCR or clinical relapse. Follow-up in both groups included PSA measurements (median of 10).

After a median follow-up of 10.6 years, 198 patients in the ART group had BCR compared with 311 in the AS group. The difference represented a 51% reduction in the hazard for BCR in favor of ART (HR 0.49, *P* <0.0001). The 10-year bPFS was 60.6% in the ART group and 41.1% in AS group and was unaffected by adjustment for baseline characteristics.

"By year 10, the cumulative proportion of patients who had started an active salvage treatment in the AS group was 47.5% compared with 21.8% in the ART group," the authors wrote. However, the clinical PFS (cPFS) benefit observed at 5 years with ART had disappeared by 10 years (70.3% vs 64.8%, HR 0.81, P=0.0539). ART significantly reduced the risk of locoregional recurrence (HR 0.45, P<0.0001) but not distant relapse (HR 0.99). The 10-year survival was 76.9% in the ART group and 80.7% in the AS group (not significant). Prostate cancer-specific mortality also did not differ significantly between groups (3.9% versus 5.4%).

The authors found significant treatment effect heterogeneity by age Younger patients and those with clear surgical margins derived significant benefit from ART in bPFS (*P*=0.0443), cPFS (*P*=0.0003), and OS (*P*=0.0008), (*P*=0.0443 for test of heterogeneity by age).

"Our results suggest that ART significantly improves bPFS and local control and might improve cPFS in patients younger than 70 years and those with positive surgical margins, although it might have a possible detrimental effect in patients aged 70 years or older," Michel Bolla, MD, of Centre Hospitalier Universitaire A Michallon in Grenoble, France, and co-authors wrote in conclusion.

MedPage Today, 18 October 2012

NEWSWORTHY ITEMS FROM CPCC

Northern California Support Group Leaders' Workshop

On October 12, 2012, CPCC held their annual Support Leaders Workshop in San Francisco, which was moderated by Stan Rosenfeld. Twelve Support Groups were represented along with several CPCC Board members and Tony Daquipa from ACS.

Dr. Matt Cooperberg from UCSF gave a very informative presentation on active surveillance. CPCC's Stan Mikkelsen gave a presentation on Support Groups helping one another. CPCC's Bill Doss gave a report on Proclamations that are intended to inform the public about Prostate Cancer Awareness and Education.

Best Practices were the **Highlight** of the Workshop.

CPCC Lists Contact Information for All Support Groups

The CPCC website lists all known Support Groups in California. In order to keep the listing up to date, please review it and notify us if there any changes in your group's listing. Please contact Stan Mikkelsen at 707-786-7009 or email swmikkelsen@suddenlink.net.

Support Group Flyers

CPCC will post flyers announcing upcoming activities for support groups on our Website's *Calendar Page*. Please note that we need as much lead time as possible. To post a flyer, please contact Stan Mikkelsen at 707-786-7009 or email swmikkelsen@sudenlink.net.

AETNA EXPANDS COVERAGE OF DENDREON PROSTATE CANCER DRUG

Health insurer Aetna Inc. said on Friday it will pay for a greater number of patients to receive sipuleucel-T (Provenge®), the prostate cancer drug made by Dendreon Corporation in Seattle, WA.

Aetna will now provide coverage for patients with metastatic prostate cancer who have failed to respond to hormone therapy and whose disease has spread to the lungs or the brain. Previously, patients whose cancer spread to the brain or lungs were not covered. Patients whose disease has spread to the liver still are not covered.

Provenge, the first personalized, therapeutic vaccine to reach the market, has taken off to a disappointing start amid confusion among physicians over reimbursement. It costs roughly $93,000 per treatment. In 2011, it generated just $213.5 million, roughly half of what the company had originally projected.

Provenge was approved in the US in April 2010 based upon the results of clinical trial showing that the drug extended median survival by 4.1 months, to 25.8 months from 21.7 months.

Reuters, 9 October 2012

BMI, BP DO NOT UP PROSTATE CANCER RISK

Results of a large cohort study showed that metabolic factors did not increase the risk of prostate cancer but modestly raised the risk of prostate cancer mortality, an article published online the journal *Cancer* concluded.

Relatively few studies have examined relationships between specific metabolic factors and prostate cancer, and most investigations have involved small numbers of patients, the authors noted in their introduction. The effect of combined metabolic factors on prostate cancer risk has a mixed history in the literature.

To expand the investigation of metabolic factors and prostate cancer risk, Christel Häggström, MSc, of Umeå University in Sweden and colleagues analyzed data from the ongoing Metabolic Syndrome and Cancer Project (Me-Can). The Me-Can database comprises 289,866 men from Sweden, Norway, and Austria and contains records of blood pressure, lipids, glucose, height, weight, and other clinical and demographic characteristics. Investigators grouped the men into quintiles on the basis of metabolic parameters and calculated relative risk for individual parameters and a cumulative risk score.

During a mean follow-up of 12 years, 6,673 men developed prostate cancer, and 961 study participants died of prostate cancer. Comparing highest versus lowest quintiles for each metabolic parameter, the investigators found that neither the individual parameters nor the composite risk score predicted an increased risk of prostate cancer. Two risk factors were associated with a lower risk of prostate cancer: fasting glucose (RR 0.82, P=0.03 for trend) and triglycerides (RR 0.88, P=0.001 for trend).

Analysis of associations between risk factors and prostate cancer mortality identified three parameters that predicted an increased risk: BMI (RR 1.36, P=0.013 for trend), systolic blood pressure (RR 1.62, P=0.001 for trend), and diastolic blood pressure (RR 1.24, P=0.001 for trend). Additionally, the adjusted composite score (z score) predicted an increased prostate cancer mortality risk (RR 1.13 for trend).

"The results of the current study add further evidence to support the hypothesis that high levels of metabolic factors, separately or combined, are not related to the development of prostate cancer but are related to an increased risk of disease progression, but with no evidence of synergy between the metabolic factors," wrote Häggström. He added that this data should encourage efforts to control these factors to decrease risks of cardiovascular disease, diabetes and perhaps prostate cancer death.

"The question now becomes 'why' "said Stephen Freedland, MD, of Duke University, who was not involved in the study. "Both elevated glucose and triglycerides are common among men with diabetes, which is an end state of insulin resistance wherein the pancreas can no longer keep up and starts to fail." He argues that low insulin is protective for prostate cancer death, which would directly support prior work by others suggesting this mechanism.

MedPage Today, 22 October 2012

DRUG AIDS SEXUAL FUNCTION OF PROSTATE CANCER PATIENTS AFTER RT

Sildenafil citrate (Viagra®) improves overall sexual function of prostate cancer patients who received radiation therapy (RT), according to trial results presented by researchers from Memorial Sloan-Kettering Cancer Center at the American Society for Radiation Oncology (ASTRO) annual meeting.

The objective of the prospective, randomized, double-blind, placebo-controlled trial was to determine if daily, adjuvant use of Viagra, a phosphodiesterase type 5 inhibitor, would preserve erectile function (EF) in prostate cancer patients. The drug has proved beneficial to men who have had a radical prostatectomy. (RP)

"We wanted to see if it could help preserve EF after RT as well" explained radiation oncologist Dr. Michael Zelefsky, vice chair for clinical research in the hospital's department of radiation oncology.

The study included 290 patients with clinically localized prostate cancer who were treated with external-beam RT (EBRT) and/or permanent interstitial implantation. They were randomly assigned to receive a 50-mg dose daily of Viagra or a placebo. Medication/placebo was initiated three days before treatment and continued daily for six months, after which the drug therapy was discontinued and taken on an as-needed basis.

Patients in both groups were asked to complete the International Index of Erectile Function (IIEF) and International Prostate Symptom Score (IPSS) questionnaires before therapy and at six, 12, and 24 months after RT.

Results from 144 evaluable patients, indicated that those in the Viagra group experienced improved overall sexual function compared to the placebo group at all time points. Patient characteristics including age, brachytherapy use, androgen-deprivation therapy, and baseline IIEF scores were similar among both treatment groups.

"The most significant improvements were seen at six and 12 months following treatment, with a slight dip at the 24-month mark," said Zelefsky. "This suggests that future clinical trials need to be conducted to demonstrate if a longer treatment can further improve patient outcomes."

Aunt Minnie.com, 6 November 2012

USPSTF RECOMMENDATIONS ARE THEIRS ALONE

Many of us have been waiting for the Secretary of Health and Human Services, Kathleen Sebelius, to take a position on the US Preventive Services Task Force's "D recommendation" on PSA testing for prostate cancer. We now know that the Secretary does not take a position on USPSTF recommendations.

The Task Force's recommendations are theirs alone. To quote Secretary Sebelius: "***The USPSTF does not set federal policy and they don't determine what services are covered by the federal government."***

Source: Secretary Sebelius, November 18th, 2009 in response to USPSTF recommendations on mammograms

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The blue ribbon is the universal symbol for *Prostate Cancer Awareness*

PSA SCREENING RATES DROP

(Continued from page 1)

significant drop in those participating just because they were generally health conscious, and a very significant drop of almost 20% for men just visiting for their concerns for prostate cancer," Poage said. "But the only good statistic that we were a little excited to see was family history. That rate doubled, which means men understand that there are significant risk factors across racial barriers for prostate cancer."

The impact from the recent recommendations against screening is evidenced in the decline seen in the Prostate Cancer Awareness Week data, and will likely be seen for years to come, however, Poage said. "We know already from the last 6 months since the most recent (USPSTF) guideline change that there has been a decrease in referrals for prostate cancer from primary care physicians," she said.

"So not only has this information impacted the public, it really has impacted how medicine is being practiced from the primary care physicians, and we certainly have a lot of work to do," she concluded.

2012 Annual APHA Meeting, abstract 267022.

Medscape Medical News, 1 November 2012

CPCC PHONE NUMBER & E-MAIL ADDRESS

For more information concerning CPCC or its programs and services, you can call us at (707) 786-7009 or send us an E-mail at cpcc@prostatecalif.org.

CPCC HELPLINE

This service is available for families and significant others of men who have been newly diagnosed with prostate cancer, are undergoing treatment or have suffered recurrent disease. Members of CPCC provide this service and are available to respond to your inquiries 7 days a week between 10:00 AM and 10:00 PM. You may call:

Stan Rosenfeld	(415) 459-4668
Erlinda Patterson (Spanish)	(909) 754-8392

CPCC WEBSITE

Go to our website <www.prostatecalif.org> for our calendar of events, legislative page, support group meetings and lending library. You can also access copies of past issues of CPCC News in PDF or Word format. There are direct links to other websites including current NCI trials.

CPCC publishes all major events in bi-monthly newsletter (February, April, June, August, October and December). We need your notice by the 9th of the month before printing. E-mail Stan Mikkelsen at cpcc@prostatecalif.org.

"YOUR CONTRIBUTIONS MAKE OUR WORK POSSIBLE"

Enclosed is my gift of $_____. **Mail to:** CPCC, P.O. Box 83446, Los Angeles, CA 90083

Online Donations may be made at www.prostatecalif.org.

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