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## WHAT TO MAKE OF THE PROSTATE CANCER SCREENING STUDIES

Two ongoing prostate screening studies, one in the US and the other in Europe, provide an early peek at mortality information. The studies, discussed in the 18 March 2009 issue of *The New England Journal of Medicine*, have caused a storm of confusion, since they seem to conflict. Actually, the studies are complementary, both make a lot of sense, and they are certain to influence medical practice even before they are completed.

For background, US health policymakers are concerned that too many people get screened with the PSA test, which can identify prostate cancer long before symptoms develop. For this slow-growing tumor, that can mean before it needs to be detected, leading to unnecessary treatment, side effects, and cost. Thus, many think PSAs should be reined in. In contrast, in Europe, where PSAs are not routinely available to screen healthy men for disease, prostate cancer mortality is higher, leading some to believe that the reins on the test should be loosened up.

The two major randomized, controlled trials, begun in the early 1990s, offer a peek after roughly 10 years of moni-

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**Us TOO**<sup>®</sup>  
PROSTATE CANCER  
EDUCATION & SUPPORT

# HOTSHEET

## May 2009

## A JOINT STATEMENT FROM AMERICA'S PROSTATE CANCER ADVOCACY, EDUCATION AND SUPPORT ORGANIZATIONS

Since 1993, when the PLCO trial was started, we have awaited its results with eager anticipation, as have others. The initial report of the results of this study – and those of a comparable European trial – published on 18 March 2009 in the *New England Journal of Medicine*, have told us 2 things:

- The studies offer conflicting evidence about the possibility of a prostate cancer-specific survival benefit associated with the regular use of prostate specific antigen (PSA) testing and digital rectal examination (DRE).
- These studies provide no convincing evidence that mass screening of men over 50 or 55 years of age will lead to a prostate cancer-specific survival benefit within 10 years.

We have come together to make two clear statements about these trials:

- Above all we thank the patients, investigators, and national authorities that funded these 2 trials for their efforts. The development and implementation of these trials over the past 16 years has been an enormous commitment by all concerned.
- We enthusiastically support continued follow-up of patients in the pros-

tate cancer arm of the PLCO study for at least 5 more years, through 2014, as originally envisaged.

In addition, in the long-term interests of the health of every man in the USA, and with health reform recognized as a national priority, we wish to state the following:

- Every man, regardless of his age, has the right to know whether he is at risk from prostate cancer, a disease that still kills over 28,600 American men every year, and many more around the world. We encourage all men to be proactive, and to seek out information and support in regard to their health.
- We shall continue to encourage every man to discuss his individual risk for prostate cancer with his doctors, and to request the appropriate use of PSA and DRE tests until better options are available. Further clinical action based on results of these tests is also a matter for serious discussion between each patient and his physicians.
- We call upon the federal government to emphasize the need for more research into early detection

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**JOINT STATEMENT**

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technologies and methods that will lead to better and more accurate diagnosis of prostate cancer.

- We call upon Congress to increase funding for the Prostate Cancer Research Program at the Department of Defense.
- We call upon the National Institutes of Health to increase funding for prostate cancer research through the National Cancer Institute.
- We call upon the medical research community to place greater emphasis on the development of new clinical tests that can differentiate between those men at greatest need for aggressive prostate cancer treatment and those with indolent forms of the disease who can be well managed without invasive treatment.

This statement is approved by the US-based prostate cancer advocacy, education, and support organizations below:

**American Urological Association Foundation** <aufacoundation.org>

**Malecare Prostate Cancer Support** <malecare.com>

**Men's Health Network** <menshealthnetwork.org>

**National Alliance of State Prostate Cancer Coalitions** <nasccc.org>

**Prostate Cancer Foundation** <pcf.org>

**Prostate Cancer International** <pcinternational.org>

**Prostate Conditions Education Council** <prostateconditions.org>

**Prostate Health Education Network** <prostatehealthed.org>

**The Prostate Cancer Mission** <pcmission.org>

**The Prostate Net** <prostatenet.org>

**US TOO International Prostate Cancer Education & Support Network** <ustoo.org>

**Virginia Prostate Cancer Coalition** <vapccoalition.org>

**Women Against Prostate Cancer** <womenagainstoprostatecancer.org>

**ZERO — The Project to End Prostate Cancer** <zerocancer.org>.

*Press Release, 23 March 2009*

**LEADING US-BASED PROSTATE CANCER ORGANIZATIONS DEVELOP JOINT POLICY AGENDA**

The prostate cancer education and advocacy community has come together to collaborate on and develop a shared agenda in the interests of the hundreds of thousands of American men who are at risk for a diagnosis of prostate cancer every year.

The leadership from eight leading prostate cancer organizations met on April 2, in Washington, DC, to explore how to effectively work together on specific policy initiatives to advocate for early detection and appropriate treatment of clinically significant prostate cancer, particularly among those men at high risk for this disease leading to the deaths of over 28,000 American men every year.

First, the eight organizations reached consensus that:

- We will continue to work with other cancer groups in support of increased federal funding for cancer research through the annual appropriations process to support the National Institutes of Health, the National Cancer Institute, and the Centers for Disease Control
- We will continue to call upon Congress to increase funding for the Prostate Cancer Research Program at the Department of Defense

Second, the eight organizations will work closely together in support of four specific initiatives:

- Passage of a Bill to create an Office of Men's Health within the Department of Health and Human Services (HHS); this Office will mirror the fine work of the Office on Women's Health
- Passage of a Congressional resolution that there is a prostate cancer epidemic among the African American community, and that appropriate research and educational initiatives are needed to combat this epidemic
- Passage of the Thomas J. Manton

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**SCREENING CONTROVERSY** (Continued from page 1)

toring and seem to affirm both views: The European study shows a mortality benefit from screening, while the American study, in which half of those in the control group (supposed to be unscreened) were unwilling to give up their PSAs, showed no benefit.

Though some pundits might dismiss 1 or the other of these studies from both sides of the pond, the 2 together provide powerful insights. Inderbir Gill, chairman of the University of Southern California Institute of Urology, believes that the studies are a huge step forward in understanding PSA screening. And “they surely serve as a moment of pause and reflection for those who might be too aggressive in treatment,” he adds.

The original plan for both studies was a head-to-head comparison of groups of healthy men who were or were not screened with PSAs. What has emerged are 2 very different trials highly influenced by the varied European and American medical practices.

In Europe, PSA screening of healthy men is not recommended routinely, and the mortality rate for prostate cancer is generally higher than in the US. The men in the control group in the European study did not have the ready option of getting PSA tests from their community doctor outside of the study. And in the screening group, the Europeans found almost twice as many cases of prostate cancers as compared with the control group.

The European results show that picking up cancers before they produce symptoms brings a 20 percent improvement in mortality, and if the analysis is done including only those people who actually got screened (some signed on but did not get tested), the benefit was 28 percent. Based on bone scans, the screened group was 40 percent less likely to have cancer that spread to bone, the favored site for prostate cancer metastasis.

However, the benefit came with a lot of overtreatment if one looks only at the first-decade mortality figures: To save one life, the European study tested more than 1,000 men and treated close to 50 of them. That’s sobering, considering the cost and side

effects of treatment – unless, of course, you’re that one man.

In the US trial, the background of medical enthusiasm for routine, yearly PSA screening had great influence. The health-conscious men who usually sign up for a research study had trouble giving up their regular PSAs.

To start with, almost half of the men entering the trial had been getting PSAs before joining, and those who did had a 25 percent lower mortality rate at the 10-year mark than the other men who joined the trial without prior testing. Once in the trial, more than half of the men in the “control” group continued to get their PSAs as part of their routine medical care outside of the study.

So, what the US trial is really comparing is a **more intensely screened group** in which 85 percent of men get their PSAs (some men in the screening group never got tested) **with a moderately screened group** where only 52 percent do. No surprise that in the control group nearly as many cancers were detected as in the so-called screened group.

It is also not surprising that the American study shows, so far during the first decade, no mortality difference between groups. From this, one could conclude that leaving the choice of whether to be screened up to men comes at no peril to public health. There is no need to try to force mass screening when moderate screening may work as well, particularly since the treatment of the disease comes with harm that many men are unwilling to accept.

In the meantime, practice continues to change. PSA screening has improved since the trials began and will get better yet. Doctors have come to recognize that watchful waiting is a sound option when a prostate cancer is small and slow growing. And regardless of their views on early screening, most urologists in the US today agree that the decision to detect and treat prostate cancer needs to be personalized, and ultimately made by the patient.

*US News & World Report, 23 March 2009*

**PSA HAS HIGHER PREDICTIVE ABILITY IN BLACK MEN THAN IN WHITE MEN**

PSA levels appear to be more predictive of prostate cancer risk in African American men compared with European American men with a family history of prostate cancer, according to results of a study published in the March 2009 issue of *Cancer Prevention Research* (Vol. 2, pp. OF1-7, 2009). However, the study team found no evidence of “race-specific” PSA, which holds that African American men have higher PSA levels at baseline and at prostate cancer diagnosis.

“It was previously thought that PSA levels were just naturally higher in African-American men, suggesting a need to possibly adjust the threshold upward before recommending a biopsy,” first author Dr. Veda Giri, director of the Prostate Cancer Risk Assessment Program at Fox Chase Cancer Center in Philadelphia, PA, explained in a written statement.

To investigate, Dr. Giri and colleagues at the University of Chicago studied 646 men at high risk for prostate cancer enrolled in the program. “We have the unique ability to study lower PSA values (< 4.0 ng/mL) because of the aggressive screening approaches being studied in the (program’s) high-risk cohort in a longitudinal fashion,” Dr. Giri and colleagues reported.

Sixty-three percent of the men in the  
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**DONATED ITEMS SOUGHT FOR JUNE 2009 US TOO ONLINE AUCTION**

Us TOO International will host our 4th Annual Online Auction June 8-23. Proceeds go to support Us TOO’s patient education and support programs and services.

To donate an item, please contact Ryan Maguire at ryan@ustoo.org or by phone at 630-795-1002.



**June 8 - June 23**

**HIGHLIGHTS FROM THE 2009 ASCO GENITOURINARY CANCERS SYMPOSIUM**

**ABIRATERONE SHOWS ACTIVITY IN HORMONE-REFRACTORY PROSTATE CANCER (HRPC)**

A majority of patients with HRPC had at least a 50% decrease in PSA levels when treated with the enzyme inhibitor abiraterone acetate, according to data from a small clinical trial.

Administered orally, abiraterone acetate inhibits the steroidal enzyme 17 $\alpha$ -hydroxylase/C17,20 lyase (CYP17), a cytochrome p450 complex involved in testosterone synthesis. In preliminary clinical trials, the agent demonstrated activity as second-line therapy for patients with HRPC.

Dr. Ryan reported findings from a phase II study involving men with chemotherapy-naïve HRPC and no prior exposure to ketoconazole at the 2009 ASCO Genitourinary Cancers Symposium.<sup>1</sup> Patients received abiraterone acetate plus prednisone daily, and they were evaluated for clinical and PSA response every 28 days.

During treatment for a median of 10.5 months, 24 patients had at least a 30% decline in PSA levels from baseline, 22 had declines of 50% or more and eight had reductions greater than 90%. Adverse events were generally mild and transient. One patient had grade 3 treatment-related hypertension.

“The results are consistent with what was observed in previous clinical studies,” said Dr. Ryan. “Abiraterone has consistently demonstrated activity in castration-resistant prostate cancer. The drug also has been generally well tolerated.” Adverse events were mild and transient. One patient had grade 3 treatment-related hypertension.

Having demonstrated single-agent activity, abiraterone acetate will be evaluated in combination with other therapies in future trials.

One or more investigators in the study had financial disclosures from Cougar Biotechnology, the study supporter, and investigators included Cougar Biotechnology employees.

1. Ryan CJ, et al, Abstract 159, presented at the 2009 ASCO GU symposium, 26-28 February 2009.

*MedPage Today, 4 March 2009*

**URINE TEST HIGHLY ACCURATE FOR DETECTING PROSTATE CANCER**

A new urine test that detects a gene fusion associated with prostate cancer is highly accurate in detecting the disease and test scores also significantly correlate with 4 indicators of prostate cancer aggressiveness.

The test, known as the T2:ERG urine test, detects the fusion of 2 genes: TMPRSS2 and ERG. It also has a sensitivity that is consistent with the roughly 50% prevalence of these gene fusions in men with prostate cancer.

At a press conference during the 2009 Genitourinary Cancers Symposium, interim results of a prospective study of 556 men tested with the T2:ERG urine test<sup>1</sup> were discussed by Jack Groskopf, PhD. He serves as the director of research and development in the Cancer Diagnostics Division of Gen-Probe Incorporated, in San Diego, CA, which developed the test.

In the study, urine specimens were prospectively collected after digital rectal exam from men scheduled for prostate biopsy. Collection sites were the San Diego VA Medical Center and Université Laval, in Montreal (n = 258), and the University of Michigan (n = 81). Prostate cancer was detected in 113 of 258 men in the VA/Laval study and in 37 of 81 men in the University of Michigan study.

In a quantitative detection of T2:ERG gene fusions in urine, there was an 84% specificity and 43% sensitivity to detection of cancer at biopsy, said Dr. Groskopf. The 84% specificity favorably compares with a 27% specificity for serum prostate-specific antigen (PSA), and the 43% sensitivity “agrees with” the fact only about 50% of all men with prostate cancer will have T2:ERG gene fusions, he said.

Also, in biopsy tissue (n = 19), T2:ERG mRNA was detected in 11 of 12 (92%) specimens that were gene-fusion positive by fluorescence in situ hybridization. Furthermore, the T2:ERG urine test significantly correlated with 4 of 5 criteria used to identify aggressive cancer at the time of

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**PROSTATE CANCER MORTALITY LOWER IN STATIN USERS**

Stephen Marcella, MD, of the University of Medicine and Dentistry of New Jersey School of Public Health in Piscataway, reported that prostate cancer mortality risk declined by 50% in men taking statins for reasons unrelated to cancer at the 2009 ASCO GU meeting.<sup>1</sup>

Investigators examined data from the New Jersey Cancer Registry and identified 380 patients who died of prostate cancer during 1999 to 2001. These men were compared against 380 randomly selected matched controls with respect to age, race, education, comorbid conditions and statin exposure from 1989 forward. Pre-specified analyses included effects of high- versus low-potency statins and hydrophilic versus lipophilic statins. The mean age of the entire study population was about 66 years.

Significantly more patients in the control group had a history of statin use (71% vs. 17%) whereas significantly more cancer patients had received antihypertensive therapy (76% vs. 53%) and other types of cardiac medications (42% vs. 28%). All differences were significant at P < 0.0001.

Unadjusted results revealed a prostate cancer mortality odds ratio of 0.49 for statin users vs. nonusers (P < 0.0001). Adjustment for demographic and clinical variables such as use of antihypertensive medications, further reduced the odds ratio to 0.37 (P < 0.0001). The benefit was greatest in men taking high-potency statins (e.g., atorvastatin (Lipitor®) and rosuvastatin (Crestor®), as well as lipophilic statins (e.g., atorvastatin and fluvastatin (Lescol®)).

Several recent studies suggest that statins decreases the risk of advanced or metastatic prostate cancer, Dr. Marcella said. “We actually looked at prostate cancer death, and we verified in every case that the patient died of prostate cancer.”

Reference:

1. Marcella S, Rhoads G, Abstract 26, presented at the 2009 ASCO GU Symposium, 26 February 2009

*MedPage Today, 27 February 2009*

HIGHLIGHTS FROM THE 2009 ASCO GENITOURINARY CANCERS SYMPOSIUM

**HIGH-DOSE, SHORTER COURSE OF RADIATION FOR PROSTATE CANCER AS EFFECTIVE AS STANDARD**

A 5-week course of high-dose radiotherapy (RT) was as effective and well-tolerated as the standard 7.5-week course in reducing the risk for prostate cancer recurrence. The study also indicates that prostate cancer has a higher  $\alpha/\beta$  ratio, a parameter used to determine the optimal dose for treating certain cancers, than previously thought.

These results are from an interim analysis of a new phase 3 study<sup>1</sup> of men with intermediate- and high-risk disease, which was presented by lead author Allan Pollack MD, PhD, professor and chair of the Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine, in Miami, FL at the 2009 ASCO Genitourinary Cancer Symposium.

In the study, Dr. Pollack and his colleagues from the University of Miami and Fox Chase Cancer Center, in Philadelphia, PA, compared biochemical failure rates in 152 men with prostate cancer randomly assigned to 38 standard intensity modulated RT (SIMRT) over 7.5 weeks (2.0 Gy per treatment; 76 Gy total dose) and 151 men randomly assigned to 26 hypofractionated IMRT (HIMRT) over 5.1 weeks (2.7 Gy per treatment; 70.2 Gy total dose, but biologically equivalent to 84.4 Gy).

After a median follow-up time of 39 months, 17% of the HIMRT group and 21% of the SIMRT group experienced a biochemical recurrence. The difference was not significant. There was also no significant difference between treatment groups in the distribution of patients by T-category, Gleason score, or pretreatment initial PSA level.

There was also no significant difference in adverse effects of grade 2 or higher toxicity between the 2 groups. The adverse effects observed most commonly were rectal bleeding and increased frequency and urgency of urination, the researchers said in a statement. However, Dr. Pollack noted possible trends towards slightly higher

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**TREATMENT WITH 5-ARI MIGHT REVEAL OVERLOOKED PROSTATE CANCER**

Almost 20% of low-risk prostate cancers (Gleason score  $\leq 6$ ) started on 5-ARI (5 $\alpha$ -reductase inhibitor) therapy either had pathologic upgrading to Gleason 7+ or had 3 or more positive cores on biopsy, Michele Lodde, MD, of Laval University in Quebec City, Quebec, said at the Genitourinary Cancers Symposium.<sup>1</sup>

In the Prostate Cancer Prevention Trial (PCPT), treatment with the 5-ARI finasteride reduced the incidence of prostate cancer by 25% compared with the placebo group. However, patients receiving finasteride had a statistically higher incidence of high-grade cancer, leading to speculation that the 5-ARI somehow induced high-grade disease. Subsequent studies, including extensive pathologic analyses have indicated that the finding was an artifact. One explanation is that finasteride-induced shrinkage of the prostate made high-grade cancer easier to diagnose.

Following the volume-reduction hypothesis of the PCPT, Dr. Lodde and colleagues began offering 5-ARI therapy as an alternative to active surveillance for men with low-risk prostate cancer. He presented findings on 113 patients studied thus far — Fifty-nine treated with dutasteride (Avodart®) and 54 treated with finasteride. Total median follow-up is 24.6 months.

Of the 113 patients, 21 (19%) were upgraded at follow-up biopsy — 15 with Gleason 7, 2 with Gleason 8 and 1 with Gleason 9 tumors. The other 3 patients were upgraded by the finding of 3 or more positive biopsy cores. Thirteen patients began treatment for prostate cancer after a median of 12 months post-diagnosis. Dr. Lodde reported that 60% of patients had negative first follow-up biopsies.

“This suggests that treatment with a 5-ARI has the potential to prevent the growth of low-grade cancer,” he said.

1. Lodde M, et al, Abstract 147, presented at the 2009 ASCO GU Symposium, 26 February 2009.

*MedPage Today, 27 February 2009*

**ESTROGEN PATCH LOOKS PROMISING AS ANDROGEN DEPRIVATION THERAPY**

Transdermal estrogen drove down testosterone and PSA levels to a similar extent as an LHRH analog, Ruth E. Langley, MD, of the Medical Research Council in London, reported at the 2009 Genitourinary Cancers Symposium.<sup>1</sup> No worrisome adverse events have occurred with the estrogen patches, which could help preserve bone mineral density, unlike conventional androgen deprivation therapy.

In a preliminary trial involving 20 patients with prostate cancer, estrogen patches lowered testosterone to castrate levels and caused no cardiovascular events, aside from one case of edema. On the basis of those results, investigators organized a multicenter, randomized study that included 172 patients and the time of this report.

The trial involved patients with newly diagnosed T3/4 prostate cancer or having PSA relapse following definitive surgery or radiation therapy. Castrate-level testosterone was defined as 50 ng/dL. The patients were randomized 1:2 to an LHRH analog or to transdermal patches that released 100  $\mu$ g of estradiol per hour.

After a planned review of data, investigators increased the patch dosage. As a result, the first 33 patients randomized to transdermal patches received 3 patches, changed twice weekly. The remaining patients assigned to the estrogen group received 4 patches changed twice weekly. Estradiol, testosterone, and PSA levels were measured at four weeks and three months and then every six months. In addition, investigators measured PSA levels at 9, 15, and 21 months.

At week four, 20/33 patients (61%) in the LHRH analog group had castrate testosterone levels as did 20/30 (67%) receiving 3 estradiol patches, and 30/33 (91%) receiving 4 patches. By week 12, 93%, 72% and 87% of patients had castrate testosterone levels in the LHRH, 3-patch and 4-patch estradiol groups, respectively. At six months, the median testosterone levels were 14.3 ng/dL in the LHRH analog

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**SELECTED MEN WITH LOW-RISK PROSTATE CANCER HAVE GOOD CLINICAL OUTCOMES WITHOUT IMMEDIATE TREATMENT**

A multi-center study of prostate cancer patients appearing in Journal of Urology on 16 March 2009 recommends that for some men diagnosed with low-risk prostate cancer, opting not to initially receive treatment can be safe if they are closely monitored.

The study conducted between 1991 and 2007 involved 262 men from 4 US and Canadian hospitals who met the following criteria: under age 75; PSA below 10 ng/ml; clinical stage T1-T2a; Gleason score 6 or below; and 3 or fewer positive cores at diagnostic biopsy. In addition, participants underwent a restaging biopsy and had no treatment for 6 months following the repeat biopsy. They subsequently underwent physical exams and PSA tests every 6 months with biopsies recommended every 1-2 years.

Forty-three patients eventually chose treatment or had evidence of cancer progression prompting a recommendation for treatment by their physician. Delayed treatment (radiation or surgery,) cured all but one of the cancers. The remaining 219 patients remained on active surveillance without evidence of metastases.

Study author Scott Eggener, MD, assistant professor of surgery at the University of Chicago Medical Center, notes there are no widely-accepted recommendations to select appropriate candidates for active surveillance or when to perform "restaging" biopsies.

Before electing active surveillance, it is important for patients to undergo a restaging biopsy following the initial diagnostic biopsy. An earlier study found that approximately 30 percent of patients were not appropriate candidates for active surveillance due to results from a restaging biopsy.

"Active surveillance ...identifies men unlikely to be affected by their cancer and encourages frequent monitoring, and then starting therapy at a later appropriate time if needed. Eggener adds that cure rates appear identical with immediate or delayed treatment.

*ScienceDaily, 22 March 2009*

**THE DOCTORS NOTE**

Dr. Gerald Chodak

This month, there is so much to discuss that not every article will get the attention it deserves. The most important articles, those addressing screening, actually will have very little impact on most readers of the *HotSheet*. The first results of two long awaited randomized studies assessing the benefit of screening have been published and they certainly have not resolved the controversy. The US study found 22% more cancers when men are intensively screened vs. routinely managed, but so far at 10 years, the mortality has not been affected. The much larger European study using less frequent screening intervals did find a statistically significant drop in mortality at 10 years. However, to save one life, over 1,000 men had to be screened and 48 treated. Both of these studies have significant weaknesses and neither has completed accumulating results. Ten years is still early when evaluating prostate cancer screening. Nevertheless, important information has been obtained.

- First, we cannot escape the fact that the benefit of screening is at best very small at 10 years and many of those men who are diagnosed with prostate cancer will get a treatment that they may not have ever needed. Does that mean screening should be discontinued? The answer is no! But it does mean that the enthusiasm for screening should be tempered until longer data demonstrates more substantial benefits? The answer is yes! Clearly, men should no longer be told that screening saves many lives, at least at the 10 year mark.
- Second, the recent recommendation to discontinue screening after age 75 or for those with less than a 10 year life expectancy is indeed supported by these data. Certainly some men in that group will choose to be aggressive even though the benefit is small, however, they should receive clear information about the small likelihood of benefit to truly evaluate their decision.
- Third, it is even more important to explain active surveillance to newly

diagnosed men and conduct more extensive studies so that we can reduce the number of men who are receiving unnecessary therapy.

The study by Eggener and others gives added support for active surveillance as a reasonable option for many men with a small risk of becoming incurable. How best to follow these men must still be determined. Perhaps new markers such as the T2:ERG urine test will offer an opportunity to identify which cancers are indeed more dangerous and in need of immediate therapy. At this time, however, extreme caution is needed before considering that this will be a better screening test or a reliable predictor. The sensitivity and specificity described thus far needs substantial improvement before it has any chance of being useful.

This issue also offers encouraging information for those needing treatment. Preliminary results with shorter, more intensive primary radiation treatment is undergoing evaluation, however the results are too premature to know its ultimate effect. For men with more advanced disease, encouraging results with both abiraterone acetate and estrogen patches may give men additional options prior to needing chemotherapy. Both treatments will need randomized studies to assess their ultimate role.

We must all hope that funding will be increased to support these and other promising studies so that further reductions in mortality from prostate cancer can be achieved.

**SURVIVORS NEEDED FOR WEB VIDEO INTERVIEWS**

Many survivors may have seen Dr. Gerald Chodak's new prostate video website at <www.prostatevideos.com> that contains over 80 videos covering every aspect of this disease.

Volunteers now are needed to create a series of patient interview videos that can help other men understand what each treatment offers from a patient's perspective. If you are interested, please contact Dr. Chodak via e-mail at gchodak1@aol.com.

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

**"Calcium supplements benefit men as much as women!"**

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

**Bottom Line:** Calcium dietary supplements seem to benefit men as much as women in terms of improving bone health, so why are most calcium supplement television commercials targeting women?

First of all, let me admit that I do owe the staff at Us TOO beer or wine or diet cola or whatever because Michigan actually made it into the NCAA basketball tournament. So, I am more than happy to pay for this but keep in mind there is a 1 drink maximum for each person and I define a drink as 1 ounce of beer, 1 ounce of wine or a half an ounce of hard liquor. In other words, you'll get just enough alcohol to fill up a very small thimble!

Now, on to the research! Benefits of calcium supplementation for older women (with and without osteoporosis) and for those taking osteoporosis prescription medications are established from research. Less known is the clinical impact of calcium supplementation for older men. To find out, researchers conducted a randomized, double-blind, placebo-controlled trial of calcium citrate supplements (600 or 1200 mg/day) versus placebo in 323 healthy men.<sup>1</sup> All men were at least 40 years old (mean age 57 years) and were followed over a 2-year period. Subjects had normal vitamin D blood levels (38 ng/mL), a low body mass index (26), and fewer than 7% of them were smokers. In short, these guys were healthy.

Results showed increased bone mineral density (BMD) at all anatomic sites in the 1200 mg/day group compared to placebo by a range of 1% to 1.5% in the lumbar spine, total hip and overall. The group receiving 600 mg/day of calcium experienced similar results to a placebo. Age and calcium intake from dietary sources did not influence the results. No difference in constipation, cramps, kidney stones, or tooth loss occurred between groups.

The authors concluded that calcium supplementation in healthy older men at 1200 mg/day had similar efficacy and safety as that observed in post-

menopausal women, but 600 mg/day of calcium was ineffective.

Have we been making a mistake by telling older men that good preventive health recommendations involve behaviors different from women? A generation of women has been raised on the importance of calcium and vitamin D supplementation for enhanced bone health. However, it seems that men, especially those with osteopenia or osteoporosis, can derive important benefits from calcium supplementation, not only for bone maintenance, but also for reducing the risk of certain kidney stones, reducing colon polyps and perhaps reducing PSA levels according to one large clinical trial.

More data is needed with regards to the long-term impact of calcium supplementation upon cardiac health, because getting too much calcium has never been shown to be healthy either.

Reference:

1. Reid IR, Ames R, Mason B, et al. Arch Intern Med 168(20): 2276-82, 2008.

**T2:ERG URINE TEST**

*(Continued from page 4)*

biopsy: Gleason score (greater than 6); the number and percent of biopsy cores positive for cancer; and cancer significance, which was based on the Epstein criteria, said Dr. Groskopf.

The T2:ERG urine test and its potential commercial application are outgrowths of basic science conducted on the fusion of TMPRSS2 and ERG genes at the University of Michigan lab, in Ann Arbor, headed by Arul Chinnaiyan, MD, PhD.

The next steps for the urine test are to confirm results showing correlation with aggressive cancer and to correlate T2:ERG urine results with pathologic features, such as tumor volume, stage, and grade in prostatectomy tissue, said Dr. Groskopf.

1. Groskopf J, et al, Abstract 3, presented at the 2009 ASCO GU Symposium, 26 February 2009.

*Medscape, 26 February 2009*

**JOINT POLICY AGENDA**

*(Continued from page 2)*

Early Detection and Treatment Act, which is focused on the provision of funds to support the early detection and appropriate treatment of clinically significant prostate cancer in underprivileged and underserved communities

- Elimination of "least costly alternative" (LCA) policies for Medicare beneficiaries

Finally, the eight organizations agreed to work closely with other relevant cancer and consumer organizations to ensure that healthcare reform includes provisions for the early detection and appropriate treatment of clinically significant prostate cancer across all sectors.

The statement above has been approved by the following eight prostate cancer organizations:

**Malecare Prostate Cancer Support**  
<malecare.com>

**Men's Health Network**  
<menshealthnetwork.org>

**National Alliance of State Prostate Cancer Coalitions** <naspc.org>

**Prostate Cancer International**  
<pcainternational.org>

**Prostate Health Education Network**  
<prostatehealth.org>

**Us TOO International Prostate Cancer Education & Support Network**  
<ustoo.org>

**Women Against Prostate Cancer**  
<womenagainstoprostatecancer.org>

**ZERO — The Project to End Prostate Cancer** <zerocancer.org>

*PRNewswire-USNewswire*  
6 April 2009



<www.FundResearchNow.org>

**PSA IN BLACK MEN**

*(Continued from page 3)*

cohort were African-American and no race-specific differences in baseline PSA levels were found when race was measured using genetic markers of West African ancestry or self-reported by participants. However, PSA had a higher prediction for prostate cancer at any given value between 1.5 and 4.0 ng/mL in self-reported African American compared with European American men with a family history of prostate cancer, they report.

For example, at a PSA of 3.0 ng/mL, the 3-year predicted probability for prostate cancer was 0.328 for European American men and 0.538 for African American men. "Clinically, our data support aggressive screening measures in self-reported African American men based on higher predictions for prostate cancer," Dr. Giri and colleagues conclude.

"African American men and men with a family history of prostate cancer should be encouraged to participate in early detection studies to define personalized screening strategies that may diagnose prostate cancer at a curable point," Dr. Giri added in a statement.

*Reuters Health, 27 February 2009*

**DURATION OF RT**

*(Continued from page 5)*

biochemical failure in the SIMRT group and slightly higher toxicity in the HIMRT group.

"Five weeks is more convenient and less taxing for patients," said Howard Sandler, MD, chair of radiation oncology at the Samuel Oschin Cancer Institute, Cedars-Sinai Medical Center, in Los Angeles, CA. Dr. Sandler is not involved in the study, but moderated a press conference where the study was discussed during the Symposium.

"This should cause a rethinking about very short radiotherapy regimens," said Dr. Sandler, explaining that regimens shorter than 5 weeks are dependent on prostate cancer having a low ratio. "The ratio is related to how fast cancers grow. The low ratio allows us to treat with less radiation," he added.

If a planned end point analysis for biochemical failure in 2 years shows no difference between the groups, that would have implications in the design of future trials, said Dr. Pollack.

1. Pollack A, et al, Abstract 4, presented at the 2009 ASCO GU Symposium, 26 February 2009.

*Medscape, 27 February 2009*

**ESTROGEN PATCHES**

*(Continued from page 5)*

group, 28.6 ng/dL in the 3-patch group, and 22.9 ng/dL in the 4-patch group. Median PSA values were 0.9, 3.2, and 1.3 ng/mL, respectively.

"These data demonstrate that estrogen patches produce a similar fall in testosterone to LHRH analogs and concomitant falls in PSA in patients with metastatic and locally advanced prostate cancer," said Dr. Langley. "The patches have been generally well tolerated."

Cardiovascular safety data have yet to be released, pending accrual of the 200-patient total for the study. Nonetheless, on the basis of the results, the data monitoring committee recommended that investigators "focus their plans towards developing a larger, phase III trial," said Dr. Langley.

Oral estrogen won support as hormonal therapy for prostate cancer in the 1960s. However, the treatment fell out of favor because it was associated with increased cardiovascular morbidity, said Dr. Langley.

1. Langley RE, et al, Abstract 173, presented at the 2009 ASCO GU Symposium, 27 February 2009.

*MedPage Today, 3 March 2009*

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OUR MISSION**

Communicate timely, personalized and reliable information enabling informed choices regarding detection and treatment of prostate cancer.



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