WRAMC Us TOO, Inc.
A PROSTATE CANCER SUPPORT GROUP
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NEWSLETTER

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♦ TO SCREEN OR NOT TO SCREEN, THAT IS THE QUESTION ♦

Two recent major research studies stirred the pot again regarding the efficacy of routine screening for prostate cancer using the PSA test and the digital rectal examination. Fourteen prostate cancer organizations, including Us TOO International, responded by issuing this joint statement:

A JOINT STATEMENT FROM AMERICA'S PROSTATE CANCER ADVOCACY, EDUCATION, AND SUPPORT ORGANIZATIONS, WASHINGTON, DC, MARCH 23, 2009

Since 1993, when the PLCO trial was started, we have awaited the results of this trial with eager anticipation, as have others. The initial report of the results of this study -- and those of a comparable European trial -- published last week in the New England Journal of Medicine have told us two things:

(1) 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).

(2) 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:

(1) Above all we thank the patients, the investigators, and the national authorities that funded these two trials for their efforts. The development and implementation of these trials over the past 16 years has been an enormous commitment by all concerned.

(2) We enthusiastically support the continued follow-up of patients in the prostate cancer arm of the PLCO study for at least a further 5 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. **(Continued on page 14)**

♦ *INSIDE THIS ISSUE* ♦

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♦ FROM THE EDITOR'S DESK ♦

The debate about prostate cancer screening continues. The experts agree that there is no definitive evidence that early screening provides a prostate cancer-specific survival benefit. On the other hand, no one can dispute that early diagnosis of the disease has led to a dramatic stage migration wherein men are being diagnosed with earlier stage, treatable prostate cancer. The crux of the matter is the ability of medical science to differentiate between indolent disease and aggressive disease, and thus prevent over-treatment with the attendant morbidities. Until then, we can expect the screening argument to continue.

On another subject, we continue to seek ways to sustain the publication of the newsletter in the face of rising postal expense and a decline in support from the pharmaceutical industry. We hope to make the decision soon for announcement in our August issue.

♦ FEBRUARY SPEAKERS' REMARKS ♦

Our February program featured a panel of men who described their experiences in dealing with prostate cancer. The program was well-received and there were enthusiastic exchanges between the panelists and the audience. A summary of the panel presentation may be seen on page 8.

♦ MEETING SCHEDULE FOR MAY 6, 2009

So much is happening in medical science affecting prostate cancer, and Walter Reed's Center for Prostate Disease (CPDR) is right in the middle of it. Dr. Stephen Brassell, a urologic oncologist at Walter Reed Army Medical Center and Assistant Director, CPDR, is well-qualified to bring us abreast of the latest promising developments in the diagnosis and treatment of prostate cancer. His topic is "CPDR Present and Future – An Overview of Clinical Trials and Trends in Prostate Cancer Management." Join us on Wednesday, May 6, 2009, at 7 PM in Joel Auditorium. Your family and guests are always welcome.

WRAMC Involved in Phase III Clinical Trial for High Intensity Focused Ultrasound. Walter Reed Army Medical Center is the latest institution to be added to a number of academic centers involved in a clinical trial that is investigating the safety and efficacy of High Intensity Focused Ultrasound (HIFU) using the Sonablate(R) 500 for the treatment of locally recurrent prostate cancer following failed external beam radiation therapy (EBRT). Some men with prostate cancer who are treated with radiation therapy have a return of their cancer as determined by a rise in their Prostate Specific Antigen (PSA). Many of these men have few alternatives other than hormone therapy.

The technology of using HIFU with the Sonablate is a minimally invasive, outpatient procedure that uses a transrectal probe to focus ultrasound energy resulting in a therapeutic rise in heat within the prostate. This results in the focal destruction of prostatic tissue. HIFU does not use radiation and is non-surgical. In a small U.S. safety trial, 91 percent of the participants treated in the study had a negative biopsy at six months.

The principal investigators at Walter Reed Army Medical Center in this study are: Major(P) Steven R. Brassell, M.D., and Colonel David G. McLeod (Ret), M.D., JD.
Eligible participants for the trial must be between the ages of 40 and 80, and have biopsy- confirmed local recurrence two or more years following external beam radiation failure. Other selection criteria are applicable for trial entry as well. Patients enrolled at Walter Reed Army Medical Center must be military beneficiaries. For more information about enrolling in HIFU trials, go to: http://www.prostatecancerrecurrenttrial.org/ or call 1-877-874-4389. (Source: USHIFU Press Release, March 16, 2009)

Early Results for 5-Day Radiation Therapy. Preliminary results show that a shortened course of radiation therapy for prostate cancer called stereotactic body radiation therapy (SBRT) provides good PSA response for early-stage prostate cancer and has the same side effects as other treatments, according to researchers at Stanford University.

Radiation therapy is an effective way to treat localized prostate cancer. Proven successful treatments include brachytherapy and external beam radiation (EBRT). EBRT therapy involves small daily doses of radiation to the prostate, five days a week, for eight weeks to give enough radiation to kill the cancer cells while sparing nearby healthy tissue. While effective, the duration of treatment can be burdensome for some patients, particularly those remote from a treatment facility. SBRT gives a higher dose of radiation every day for five days.

In this study, King, et al., treated 41 men with low-risk prostate cancer with SBRT. After a median follow-up of 33 months, no man in the study has seen his cancer return. Men in the study reported side effects, including urinary and rectal problems that were no better or worse than with other prostate cancer radiation treatments. The researchers conclude that these early results are promising in the effort to reduce the duration of radiation treatment while possibly improving its effectiveness. However, they note that it can often take as long as 10 years to see late side effects and recurrences, so the men in the study will continue to be monitored closely. Further follow-up research will be necessary to establish that SBRT is as effective in the long term as other proven treatments for early-stage prostate cancer. (Source: *inter'l J of Rad, Onc, Biol, Phy*, March 15, 2009, via Science Daily News, March 16, 2009)

Alcohol is Great for Your Heart, But Not So Good for Your Prostate! An international team of scientists from Australia, Canada and the U.S. have concluded after a review of 35 studies that alcohol consumption may impact the risk of developing prostate cancer. The researchers found men who drink 14 standard alcoholic drinks a week or more have a 20 percent greater chance of developing prostate cancer than those who drink less. These findings clash with previous research indicating drinking two or more alco-

holic drinks a day could prevent heart attacks. Further research is needed to determine both benefits and health risks related to alcohol consumption and different types of disease. Chikritzh, et al., Australia's National Drug Research Institute, say that men with a history of prostate cancer or other indicators that would make them likely to develop the disease should think seriously about keeping alcohol to a minimum. (Source: ZERO, Vol. 5, No. 27, March 17, 2009)

PSA Predictive Ability for Black Men. Giri, et al., Fox Chase Cancer Center, Philadelphia, and the University of Chicago, studied 646 men at high risk for prostate cancer. Sixty-three per cent were African-American. The PSA test had a higher predicted probability of prostate cancer at values between 1.5 and 4.0 ng/mL for African Americans compared to European-American men. For example, at a PSA level 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. The researchers said their analysis supported aggressive screening measures in African-American men based on higher predictions of prostate cancer. (Source: Cancer Prev Res 2009:2:OF1-OF2 via Reuters Health Information, February 27, 2009)

PSA Screening in Men Over 75. New data supports discontinuing screening for prostate cancer in men older than 75 years, but only in men who have low levels of prostate-specific antigen (PSA ≤3 ng/mL). Schaeffer, et al., Johns Hopkins University School of Medicine, Baltimore, say this group is unlikely to develop aggressive prostate cancer or to die of this disease during their remaining life. Not screening these older men would dramatically cut costs and would eliminate harm from additional evaluations and/or treatment in a population unlikely to experience benefit. The researcher analyzed serial PSA measurements in 849 men, of whom 122 developed prostate cancer.

The study conclusions differ from earlier recommendations which advised stopping screening in all men who are 75 years or older. However, this study found that all men older than 75 years of age may not be equal in risk.

This new study has not gone unchallenged. One observer comments that there are still many questions about whether PSA testing identifies clinically significant disease and about how effective treatment is in older patients. In fact, a recent update of the Scandinavian Prostate Cancer Group-4 trial showed no benefit associated with radical prostatectomy for men older than 65 years. Another viewpoint says that for men who are 75 years and older and others who have a life expectancy of 10 or fewer years, the incremental benefit from treating their prostate cancer detected by screening is "small to none." (Source: *J Urol*. 2009; 181;1606-1614, via Medscape Medical News, February 20, 2009)

Urine Test May Identify Aggressive Prostate Cancer. Researchers say their study indicates that an experimental urine test is "at least as good" as the prostate-specific antigen (PSA) test for predicting which men have aggressive prostate cancer. Wei, et al., University of Michigan Medical School, Ann Arbor. The urine test, which assesses levels of prostate-cancer-specific metabolites, could eventually be added to PSA and other tools for monitoring prostate cancer progression. However, the new study had a small sample, and the scientific approach to analyze metabolites as prostate cancer biomarkers needs further validation and development, according to the researchers.

The new study is the first time that "metabolomics," which surveys the metabolite composition of cells and tissues, akin to the way genetics surveys their genetic composition, has been shown to solve a real-world problem. The researchers believe that one of the metabolites, sarcosine, has the potential to differentiate between benign prostate tissue and localized/metastatic prostate cancer. The Michigan researchers emphasized that their urine test is not a screening test and state that much more work has to be done before it can be used as a screening test. (Source: *Nature*. 2009.457:910-915, 799-800, via Medscape Medical News, February 12, 2009)

Thalidomide for the Treatment of Biochemically Recurrent Prostate Cancer. Thalidomide may help in the treatment of men who have biochemical recurrence of prostate cancer or a rise in their prostate-specific antigen (PSA) count after definitive primary therapy, according to a new study from the National Cancer Institute. The researchers point out that intermittent ADT is increasingly being used in patients with biochemical recurrence, and there might be a role for instituting early treatment.

All patients in this study had androgen-dependent adenocarcinoma of the prostate and two consecutively increasing PSA counts after local definitive therapy with radical prostatectomy, radiation therapy, or cryosurgery. The use of thalidomide was associated with an increase in PSA progression-free survival after intermittent androgen-deprivation therapy (ADT). However, the study's use of ADT in men with biochemical recurrence was questioned by some observers. Larger studies with longer follow-ups are needed to determine the usefulness of thalidomide in this setting, note the study authors. (Source: *J Urol*. 2009;181:1104-1113, via Medscape Medical News, January 28, 2009)

Prostate Cancer May Cause Neglect of Other Illness. The majority of men with early-stage, low- or moderate-grade prostate cancer die from causes other than prostate cancer, according to a recent study. Therefore, prevention and management of other health conditions is important in these patients. Goodwin, et .al., University of Texas Medical Branch, Galveston, assessed the outcome of 208,601 men between the ages of 65 and 84 years diagnosed with prostate cancer from 1988 through 2002. Overall, 59.1 percent of the entire group had early-stage prostate cancer with low- to moderate-grade tumors.

The researchers say that once a diagnosis of cancer has been made, it often becomes the sole focus of medical care. This is understandable, because cancer is typically life threatening and often requires aggressive therapy. But earlier cancer diagnoses, due to screening, and improvements in treatment have been associated with lower cancer mortality. Thus, patients are living longer after a diagnosis of cancer, to the point where other illness may have a substantial effect on their survival, the researchers say.

The mortality in these patients was similar to that of men the same age without prostate cancer. Among the men with early-stage, low- or moderate-grade tumors, mortality from prostate cancer was 2.1 percent versus 6.4 percent from heart disease, and 3.8 percent from other cancers.

Treatment decisions for localized prostate cancer should consider life expectancy based on age and the contribution of other conditions to the patient's mortality, the researchers note. Also, the decision to use androgen deprivation therapy, which is now commonly used to treat even early-stage prostate cancer, must be made carefully if another significant illness is present. Overall, the team concludes that older men with early-stage prostate cancer would be well served by an ongoing focus on screening and prevention of cardiovascular disease and other cancers. (Source: *Journal of the American Geriatric Society*, January 2009, via Reuters Health, January 27, 2009)

More on Active Surveillance AKA Watchful Waiting. Active surveillance appears to be safe for selected prostate cancer patients. Guillonneau, et al., Memorial Sloan-Kettering Cancer Center, New York, studied 268 men younger than 75 years old who had multiple treatment options but ultimately chose active surveillance. The patients had a PSA level no higher than 10 ng/mL, clinical stage T1-T2a disease, a Gleason score of 6 or lower, and no more than 3 positive cores at diagnostic biopsy. They had a restaging biopsy immediately before active surveillance began and no treatment in the following 6 months.

Over a median follow-up of 29 months, 43 patients received treatment; 41 of them had no disease progression at a median of 23 months following treatment. At two years, the probability of staying on active surveillance was 91%. At 5 years, it was 75%. Patients with cancer found on the second biopsy and a higher total number of cancerous cores were significantly more likely to undergo treatment. Other factors, including age, PSA

and clinical stage, were not associated with outcome.

According to the researchers, the study indicates that 75% of the patients who are real candidates for active surveillance will still fulfill the same criteria 5 years later, demonstrating the absence of noticeable progression. They also said that active surveillance, based on strict criteria and a repeat prostate biopsy might be a way to distinguish between patients with a growing tumor that requires treatment and those whose tumors will remain indolent. These patients require continuing monitoring, but many of them will not have disease progression and will not require any kind of active and treatment. (Source: *J Urol* 2009; 181:1635-1641 via Reuters Health Information, March 31, 2009)

Cancer Death Rates Decline Among Blacks. Black Americans' cancer death rates continue to decline, according to an American Cancer Society report. However, they are still diagnosed at more advanced stages of cancer than whites, and blacks have lower survival rates at each stage of diagnosis of most types of cancers. There will be about 150,090 new cases of invasive cancer diagnosed in U.S. blacks in 2009 and about 63,360 cancer deaths. The most commonly diagnosed cancers will be prostate (34 percent), lung (16 percent), and colon and rectum (10 percent).

Cancer of the lung will be the most common cause of cancer death in both black men (31 percent) and women (23 percent), followed by prostate cancer in men (12 percent) and breast cancer in women (19 percent). Cancer of the colon/rectum and pancreatic cancer are expected to be the third and fourth most common causes of cancer death for both black men and women.

Death rates for all cancers combined have decreased faster among black men than white men, mostly due to rapid declines in lung and prostate cancer death rates among black men. Overall, cancer death rates have also decreased among black women but at a slower rate than among white women, likely due to smaller decreases in breast and colorectal cancer death rates among black women. While racial disparities are decreasing, the 2005 death rate for all cancers combined was 33 percent higher in black men and 16 percent higher in black women when compared to that of white men and women, respectively. The report points out that the causes of these disparities are complex and likely reflect social and economic disparities, not biologic differences. (Source: *HealthDay News*, February 18, 2009)

Dietary Fiber Intake and Prostate Cancer Risk. It has been suggested that dietary fiber may reduce prostate cancer risk, possibly by increasing circulating levels of sex hormone-binding globulin, which is inversely associated with risk. A recent European study says that dietary fiber intake is not associated with the risk of prostate cancer.

Allen, et al., University of Oxford, UK, used data collected from 142,590 men using validated dietary questionnaires. During an average follow-up period of 8.7 years, prostate cancer was diagnosed in 2,747 men. They found no significant association between total dietary fiber intake and prostate cancer risk. Calibrated fiber intake and fiber derived from fruit was associated with a small reduction in risk for total prostate cancer and for localized disease, but these associations were not statistically significant, according to the researchers. However, there was a statistically significant inverse association between calibrated intake of fiber from fruits and late onset prostate cancer risk (cancer diagnosed at age 65 years and over). (Source: *Int J Cancer* 2009;124:245-249, via Reuters Health Information, January 23, 2009)

Now They Tell Me! Frequent masturbation in young men is linked to higher risk of early prostate cancer, but it lowers prostate cancer risk for men in their 50s, according to a recent study. High levels of male sex hormones, or androgens, may increase a man's risk of prostate cancer. But different studies have reached different conclusions. This team of researchers at looked at whether men with more intense sex drives were at higher risk of prostate cancer. Dimitropoulou, et al., University of Nottingham, UK, obtained detailed sexual histories from 840 men. About half the

men got prostate cancer by age 60, and about half did not have cancer.

The findings were interesting. Sexual intercourse did not affect prostate cancer risk. But frequent masturbation did--in different ways and at different times of life. The researchers found that frequent masturbation during men's 20s and 30s increased their risk of prostate cancer, but men in their 50s who masturbated frequently had decreased risk. For men in their 20s, "frequent masturbation" was two to seven times per week. Compared to same-age men who reported masturbating less than once per month, 20-something frequent masturbators had a 79% higher risk of prostate cancer by age 60.

For men in their 50s, "frequent masturbation" was one or more times per week. Compared to same-age men who reported never masturbating, 50-something frequent masturbators had a 70% lower risk of prostate cancer. The study suggests that young men genetically predisposed to have hormone-sensitive prostate cancer will be at higher risk if their bodies naturally produce high levels of male hormones -- the same hormones that give them an intense sex drive. Masturbation itself does not increase prostate cancer risk. More frequent masturbation may just mean more sex drive and more androgens bathing prostate tissues.

On the other hand, the study suggest that in older men, masturbation itself may actually be helpful, ridding the prostate gland of fluids that may contain cancer-causing substances. In maturity, it may be more important that toxins get flushed out of the system. The researchers hasten to add that these are just theories, and more research is needed to determine the exact role of sex hormones and sexual activity in prostate cancer risk at different stages of life. (Source: *BJU International*, January, 2009, via *WebMD*, January 27, 2009)

Prostate Cancer Among Low Income, Uninsured Men. The proportion of American men with organ-confined, low-risk prostate cancer has increased significantly during the last two decades. Miller, et al., sought to determine if this positive trend extended to men at socioeconomic disadvantage by evaluating trends in prostate cancer severity in an ethnically diverse cohort of low income, uninsured men served by a state-funded public health program in California.

The study involved a retrospective cohort study of 570 disadvantaged men enrolled in the California program from 2001 through 2006. It defined two measures of cancer severity: (1) the proportion of enrollees with metastases at diagnosis, and (2) the proportions of men with nonmetastatic tumors whose cancers had low, intermediate or high risk features at diagnosis.

Prostate specific antigen levels at diagnosis exceeded 10 ng/ml for 51% of enrollees, 50% had a Gleason score 7 or greater and 43% had clinical T-stage T2 or greater. Of disadvantaged men, 19% had metastatic cancer at diagnosis and this proportion remained stable over time. Among men with nonmetastatic cancers, 24% had tumors with low risk features and the proportion of low risk cancers did not increase over time.

The study concluded that, unlike the broader United States population, the proportion of disadvantaged men with organ-confined, low risk prostate cancer has not been increasing. It said that while much attention focuses on potential over-diagnosis and over-treatment of men with screen detected prostate cancer, the findings suggest that for low income, uninsured men, under-detection and under-treatment remain significant concerns. (Source: *AWARE*, Volume 5, No. 20, January 27, 2009)

DEALING WITH PROSTATE CANCER – OUR STORIES
Five Prostate Cancer Survivors Relate their Personal Experiences

(A summary of a presentation to the WRAMC Us TOO Chapter on February 4, 2009)

RADIATION THERAPY AFTER SURGERY
by
Patrick Wesley

Introduction. My name is Patrick Wesley and I am a retiree from the Army Nurse Corps. This is the first time that I have participated in a support group. I have always been proud to be a health care provider but prostate cancer put me on the receiving end of the military health care system. As I listened to the gentlemen on this panel I was impressed with the courage they exhibited in telling their stories. My story isn't quite as complex as theirs, but I think it will reinforce the concepts that they have been sharing with us. As I prepared my remarks I reflected on the fact that my wife Linda and I are both cancer survivors. Linda had her fight with cancer about 15 years ago and her experiences prepared us as a family to cope with prostate cancer. The strength, fortitude, the positive attitudes and the humor displayed this evening will foster a positive attitude. So I think it is very important to hear these stories; it's really important for me.

Getting Diagnosed. I had just turned 50 and I was practicing what I always preached about preventative health care when I sought a check-up. During the digital rectal examination the doctor uttered several "ahems." Sure enough, a prostate biopsy was indicated. The results led to a diagnosis of benign prostatic hyperplasia (BPH), and that was that, or so I thought! Then at age 55, I experienced considerable foot pain that required surgery. As part of the pre-operative procedure, I had some lab work done. My primary care doctor suggested that a PSA test might be in order because the standards of care for African Americans my age encouraged the procedure. It revealed that my PSA was "slightly elevated." The foot surgery went off OK, and I proceeded to ignore the status of my PSA. My doctor persisted in her recommendation that I have a follow-up PSA test., so I did. My PSA was even higher so another biopsy was performed. I convinced myself it would replicate the earlier biopsy by confirming a diagnosis of BPH. I was wrong—it was prostate cancer.

My wife and I were together at the time we got the news. It didn't shock me as much as I thought it would, probably because we had been through these processes in her case. I also had the benefit of the patient education process at Walter Reed. It provided me with the information and insights I needed to understand the available treatment options. After discussing treatment alternatives with my urologist, I opted for the radical prostatectomy because, like some of the other panelists tonight, I wanted the cancer out as quickly as possible.

Getting the Bad News. My recovery from the surgery was uneventful and my one-month follow-up included a review of the post-operative pathology report. I had already obtained a copy of the pathology report for filing a VA claim. Relying on my own medical training, I focused on words like "small," "moderate," and "differentiated." I even thought that the surgical margins were negative. I interpreted all this to mean that "I'm out of the woods", but that was probably what I wanted to hear. I didn't see the other words within the report indicating that the cancer was beyond the prostate. We were so confident that I would recover from my surgery and continue with my life that my wife left town for a family reunion and I went to see my urologist alone.

My urologist told me that I should have external beam radiation therapy to address the fact that the cancer was outside the capsule. Consultation with the radiation clinic revealed that I would not have the standard 25-day regimen. Rather, it would be more like 60 days! I joked that I had a cousin who was arrested for armed robbery and he didn't get that kind of time!

Dealing with Incontinence. At the time, I still had not recovered from my post-surgery incontinence; I was using 8 to 10 pads a day. It wasn't anticipated that the radiation therapy would worsen my incontinence, but I began to use even more pads following radiation therapy. I was getting very miserable about my reliance on pads, especially since I was back to work. I learned that it would be about two months before follow-up PSA testing would provide information about the success of the radiation therapy. The combination of the two-month wait and my worsened incontinence made me apprehensive, so I sought help. I was started on medical management for incontinence using the medication imipramine which is basically an antidepressant, but it has a secondary use for treating enuresis. It took thirty days of the medication to get me to therapeutic level. My incontinence was worse at the end of the thirty days! I kept being reminded that I had to give Mother Nature a year or so for the natural recovery of continence after a radical prostatectomy. So there was an initial reluctance to treat me further at that time. Fortunately, I was able to convince the urologist to conduct a eurodynamic test to check the condition of my bladder and its capacity. The test led to the conclusion that my best alternative for incontinence was the implantation of an artificial urinary sphincter (AUS). I have had an AUS for about four months now and it is working very well after my body adjusted to it and I became more adept at employing it. It has taken me from 8-10 pads a day to one and I am not sure if I even need it.

Aftermath. So, how am I doing! Just fine, thank you! The post-radiation PSA tests say my PSA is undetectable (less than 0.01). The AUS is getting the job done. Listening tonight to the other panelists who have faced more difficult situations gives me confidence that should I have recurrence there are therapies available to deal with it. I turned 60 yesterday and tomorrow my brother Thomas undergoes a radical prostatectomy. As he faces uncertainty, we are closer than ever. Now let me make an additional comment based on my own experience. I see three aspects in dealing with a diagnosis of prostate cancer. The first is gaining an understanding of the disease itself. Next is to become fully informed about the various therapies that may be available to you—their likely outcomes and their potential side effects. And finally, engage your support system (family, friends, support groups such as this one) by involving them, as appropriate, in every issue confronting you. I want to close by saying that I am doing very well thanks to the military medical system, the superb medical staff that cared for me and the family and friends who are my magnificent support system.

DEALING WITH RECURRENCE
by
Ray Walsh

Getting Diagnosed. Good evening, my name is Ray Walsh and I have been a cancer patient for ten years. I prefer to refer to myself as a patient rather than as a survivor. I am not a survivor, I am a lifetime patient. In 1997, I was a platelet donor at Walter Reed when a PSA screening was offered. It was September 1977 and my initial PSA was 1.8, but it rose to 7.3 by April 1999. A biopsy revealed a Gleason 7. I was 64 years old and I had prostate cancer.

Selecting a Therapy. I had no other health problems worth mentioning at that time. I considered all the available therapies—surgery, external beam radiation, brachytherapy—but not for long because I wanted the cancer out of my body. So I underwent a radical prostatectomy on July 20, 1999. The bad news came with the arrival of the post-operative biopsy report. It revealed a Gleason 9; the harvested lymph nodes were clear, and the margins were negative, but cancer cells were found in my seminal vesicles and the cancer was aggressive. Recurrence was likely.

Recurrence. Sure enough, about two years later in July 2001 my PSA rose. At that time, Walter Reed was using a PSA of 0.4 as an indicator of recurrence after primary therapy. Now we needed to confirm that the cancer indeed was back. The first action was a bone scan to detect cancer spread; it was negative. Next we turned to the more sophisticated Prostascint that looks at soft tissue. The Prostascint was positive--I had cancer cells running around in my body! I was now graded as a T-3 with metastatic prostate cancer. We began considering treatment alternatives because something had to be done. Salvage radiation was a likely option, but I was apprehensive about it because in the meantime I had developed certain intestinal problems. I feared that salvage radiation would only aggravate that condition. Instead, I started hormone therapy immediately.

Hormonal Therapy. First choice was high dose Casodex (150 mg per day**)** which seemed effective, but it was having a detrimental effect on my liver functions so the Casodex was stopped. A second bone scan revealed metastasis to the bones of my rib cage. In November 2002, I started a regimen of two flutamide capsules daily and Zoladex injections every three months. I also had the opportunity to participate in a clinical trial with the drug Zometa that was showing promise in the treatment of breast cancer. Would it be effective in treating prostate cancer? Men undergoing hormonal therapy are susceptible to osteoporosis because hormonal therapy blocks the production of testosterone so essential to bone health. Even more important, there was evidence that Zometa could retard metastasis of prostate cancer cells. It worked for me because my subsequent bone scans were very favorable.

I took Zoladex by injection quarterly until July 2005 when a tiny titanium capsule, called Viadur, was implanted in my arm. It feeds leuprolide acetate continually as part of the treatment for hormone deprivation. Men on hormone therapy have regular PSA testing to monitor the effectiveness of their medications. In my case, I was taken off flutamide because of rising PSA and the low-dose Casodex again because of adverse liver impact. I am currently on a drug called Ketoconazole together with hydrocortisone. Ketoconazole tends to affect your steroids, so the hydrocortisone is prescribed to offset it. Like all medications, there are potential side effects, such as nausea, weight gain, headaches, sleep disorder, and constipation. The Viadur implant in my arm was replaced by product called Vartas because the manufacturer of Viadur stopped production.

After I finished Zometa clinical trials the results were so good that it was decided to keep me on Zometa. I have remained on Zometa for about seven years now, adjusted in accordance with the judgment of my medical advisors. I have been on Ketoconazole for over 2 years now. My testosterone was less than 2 at last measurement. This compares with a normal range of 280 to 800. Yes, my libido is affected to some degree, but I still appreciate feminine beauty, so I'm not dead yet! Ketoconazole is not approved by the FDA for treatment of prostate cancer, so it's an off-label application. It is designed to treat fungus, but doctors noticed it had a decided benefit in reducing testosterone. It is working for me.

Aftermath. I am now at the point in my hormone deprivation therapy where the conventional drugs have been employed. If my PSA begins to rise again, then chemotherapy is the remaining option—an unwelcome alternative. Nevertheless, my PSA has been undetectable at less than 0.010 for over two years based on my current drug regimen. There are side effects from all of them, but they are tolerable. Side effects include hot flashes, loss of energy, and breast tenderness and enlargement, for example. The side effects vary from person to person so I am very happy with my current lifestyle, and if the PSA remains stable, then I'll be OK.

In one respect, I have been able to deal with my prostate cancer over the years because I observed cancer's course in my daughter who valiantly battled breast cancer until it ultimately claimed her after eleven years. During the course of her treatment, she taught me a few things about how to live with cancer.

Finally, I should mention that incontinence after my radical prostatectomy has been persistent from day one, even when I had a Foley catheter in place after surgery, and I drain to this day. I eventually had an artificial urinary sphincter implanted, but it has not been without complications.

(In rely to a question about incontinence, Ray Walsh made these comments:)

The artificial urinary sphincter (AUS) changed my entire attitude about incontinence because I felt I was largely back in control. It reduced my pad usage from 10-12 pads per day down to 1 or 2. The cuff of the AUS is surgically placed around the urethra at the bladder neck. Over time, tightening and relaxing the cuff can lead to erosion or atrophy of the urethra. This may result in a less than complete closing of the cuff resulting in some leakage. According to my surgeon, this apparently is what is happening in my case because I find myself using more pads than in the past. I try to compensate for this by controlled urination, i.e., I schedule myself to urinate every hour or two.

VACCINE THERAPY FOR PROSTATE CANCER
By
Philip Brach

Introduction. The title of my presentation is "The Flip Side of Prostate Cancer" because I am quite flippant about my disease. I think it helps to have a humorous approach to it. I will give you a quick history of my initial treatment. It was the Wednesday after Labor Day in the year 2001. An 11-year old boy in a public school in Southeast Washington said, "You look sick." Asked how he could tell, he said, "I can see it in your eyes." By the end of the week I had been diagnosed with prostate cancer!

Vaccine Therapy. I had a PSA of 14.7 and a biopsy showed a Gleason score of 8. I didn't even know what a DRE was, but I soon found out! I had always thought it stood for "Director of Religious Education!" After the biopsy I was sent directly to an oncologist because, as I subsequently learned, at that time a Gleason 8 indicated a 50-70 percent likelihood that the cancer had escaped the prostate. No need to waste time with surgery and its attendant side effects. I asked the oncologist, no pun intended, what is at the cutting edge in this business and he mentioned research efforts at the National Institutes of Health (NIH), and asked if I were interested in participating. I certainly was because I hadn't heard much that I liked about the conventional therapies such as radiation or hormonal therapy that were available to me. So I hustled over to

NIH and enrolled in a phase 2 clinical trial that sought to determine if vaccine therapy could result in a natural immunity to prostate cancer. The vaccine was designed to stimulate my immune system to recognize and attack the cells making PSA. I received a monthly vaccine injection supplemented by self-injections at home. Since the clinical trial was an experimental protocol, I also was referred for conventional radiation therapy as a precaution. The original plan was that I have both brachytherapy and external beam radiation, but eventually I had only three-dimensional conformal radiation, mid way through the vaccine protocol. Upon completion of the vaccine trial my PSA was undetectable and remained so until the summer of 2007. In retrospect, I am more than satisfied with the choice of the vaccine protocol that I made, even if the results have not turned out as well as I had hoped.

Recurrence. In May 2007 my PSA started to creep up; by August it was doubling every two weeks! So it was back to the NIH. Participation in other clinical trials was considered, but for various technical reasons I was ineligible. Finally I was able to get involved in an effort to eradicate a single metastatic lymph node. There is emerging evidence that if one or more metastases that may still be curable, they are worth being managed aggressively. This involves what is called stereotactic radiography, which is a high dose and relatively limited. Because mine was a lymph node and these can spread in contiguity, my nodes above the previous field were also treated to be sure. The tricky part is getting in enough doses to be able to eradicate the disease. In addition, I also began conventional hormonal therapy. A previous encounter with hormonal therapy was unpleasant, but this time I was determined to deal with it. At present I am on a 3 month cycle of Lupron.

Where I Stand. My PSA is now down below 1.0, still detectable, but I am relatively happy about it. Of course, there are some of the common side effects such as the bowel problems associated with radiation therapy. So as they say at American Express, I never leave home without a pad and Imodium! I have been very happy with the treatment I have received. I am comforted by the possibility that my involvement with clinical trials at NIH may some day make a difference for other men. I encourage men dealing with prostate cancer to consider participation in clinical trials that may be applicable to them. I am grateful to so many—the medical staffs that have served me well, family and friends for their support, and the camaraderie and the support of the men, such as you here tonight, who understand what others are going through. Together we often joke about our predicament. Sometimes we may be honest and admit how badly we feel, but when we do, we know that there is someone else who really understands us. Thank you for listening. (**Editor's note**. Subsequent to his panel presentation, Philip Brach again has a rising PSA and is assessing his options. He says, "Keep tuned for updates and keep me in your prayers.")

DEALING WITH RECURRENCE
By
Thomas Bass

Getting Diagnosed. Good evening. I was diagnosed with prostate cancer in 1988, twenty-one years ago at the age of 55. I am now 77. At the outset, my urologist said my PSA and Gleason score were such that I could choose either a radical prostatecectomy or radiation. I chose surgery because I wanted to get the cancer out just as you have heard from the other panelists tonight. But during the operation the surgeon detected that the disease had spread to my lymph nodes. So the operation was stopped, and after my recovery I underwent a 25-session regimen

of radiation. Unfortunately, my PSA began to rise again after about three months. In those days, I suppose, orchiectomy (surgical removal of the testicles) was the primary therapy to eliminate testosterone from feeding the cancer. Nowadays, hormonal therapy would probably be the alternative. At any rate, I had the orchiectomy. At the time I didn't know what an orchiectomy was, but I soon learned! But it didn't solve the problem and after four months my PSA continued to rise.

Flutamide, an antiandrogen, was the next attempt to control my PSA. It was effective for about a year, then the same story—a rising PSA. The next resort was to Casodex, another antiandrogen, but after another year or so my PSA kept going in the same direction—up! So my prostate cancer had become hormone refractory. It was recommended that I enter a clinical trial, and I did so. It is a BNIT Vaccine Trial, an open label, dose-escalation vaccine trial for men with hormone refractory prostate cancer. Although my PSA is high at 24, it is holding steady and my doctors are pleased with that. In the meantime I have not experienced any side effects from being involved in the clinical trial. In short, after 21 years with prostate cancer and having experienced the gamut of therapies to cope with a rising PSA, I am still hoping for the best.

BLADDER CANCER AND PROSTATE CANCER
by
George Enders

Bladder Cancer. I live in a very unique place here in Washington, D.C., and all you gentlemen are invited to come live there too. It's called the Old Soldiers Home. And we are old, believe me! I am old—I'm 84. But let's forget about that. Well, I learned the hard way that I had bladder cancer. It was 2:00 am on May 22, 2006. I had to go to the bathroom and noticed that I was passing blood, a lot of it. My condition was beyond the capability of the local dispensary, so I was referred to the Urology Clinic at Walter Reed later that day. I told the lady at the desk about my referral and asked to see a doctor. She said she could get me an appointment two weeks hence! I said, "I'm sorry ma'am, but I'm urinating blood now, and I don't know what I will be urinating two weeks from now!" That did the trick. They rushed me to an examination room and the doctor announced he was going to perform a cystoscopy to inspect my bladder. I didn't know what that was, but I soon found out! So he went up there, looked around, and sure enough, there it was—a one centimeter cancerous tumor hanging down like a chandelier from my bladder. The doctor was able to remove it then and there while I was still halfway conscious. Fortunately, it had not invaded the muscle, so I still have my bladder. I'm told that many men treated for bladder cancer end up wearing a bag for the rest of their lives, so I count my blessings.

There was a ten-week follow-up routine. A solution would be placed in my bladder for about two hours, and after urination, a specimen was collected for analysis. After two three-month intervals, I went for a follow-up cystoscopy. They said "everything looks hunky-dory, come back in a year." So much for my bladder cancer!

Prostate Cancer. The year is up, and I'm back to the Urology Clinic as instructed. The doctor said that there were indications that I should have a biopsy of my prostate and I did. After several other procedures, I got the news. Guess what? I had prostate cancer and it had already spread to my ribs and spine! That's a big problem, isn't it, ladies and gentlemen? I told myself,

"Don't worry about it. As soon as you start worrying about it, it is going to get the best of you. Just do what needs to be done."

Given my age and the fact that the cancer had already metastasized, my options were limited. I was referred to the Center for Prostate Disease Research (CPDR) where a team of specialists reviewed my situation for action. I began hormonal therapy, but after a while my system became tolerant to the medications. Next, they suggested I enter a clinical trial and they explained what was involved. After I agreed to participate, they again reviewed my situation to ensure that the clinical trial was suitable for me. Some men resist participation in clinical trials, perhaps because there is no guarantee that it will help them personally. But that's not how I felt. My participation just might help me, but even more important, it may help other men deal with their prostate cancer in the future. So that is why I enjoy being in this program, and besides, the CPDR staff treats me like a prince! The clinical trial is a double-blind study, so I don't know if I am getting the medication or the placebo. Nevertheless, I feel better overall, so just maybe it's working for me. Each procedure takes about two hours. Blood is drawn, processed, and then subsequently replaced back into my system. They have a beautiful selection of movies that I watch throughout the procedure.

Ladies and gentlemen, I feel privileged to appear before you tonight. As you can tell by now, I'm not all that big on the medical details like PSAs, Gleason scores, etc. Instead, I put my trust in the medical staff here at Walter Reed. It's been working for me. And, hey! I'm 84 years old! Thank you very much for listening to me. (**Editor's note:** George Enders is enrolled in the Dendreon Phase 3 Clinical Trial at WRAMC. Dendreon (Provenge) stimulates the patient's own immune system, the body's natural mechanism for fighting disease, to recognize and destroy prostate cancer cells.)

(Prostate Cancer Screening – continued from page 1)

- We call upon the federal government to emphasize the need for more research into early detection 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 following US-based prostate cancer advocacy, education, and support organizations:

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

♦ WRAMC US TOO COUNSELORS ♦ (As of May 1, 2009)

(THESE PERSONS ARE WILLING TO SHARE THEIR EXPERIENCES WITH YOU. FEEL FREE TO CALL THEM.)

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MAJOR (P) STEPHEN BRASSELL, MC
Urologic Oncologist
Assistant Director, Center for Prostate Disease Research
Walter Reed Army Medical Center

♦ TOPIC ♦

An Overview of Clinical Trials and
Trends in Prostate Cancer Management