Many of you are familiar with the Department of Defense’s Congressionally Directed Medical Research Programs (CDMRP). The CDMRP provides research funding in several medical research areas including prostate cancer, and it relies on prostate cancer survivors to assist in prostate cancer funding decisions. You can help direct funding to critical prostate cancer research projects by serving as a Consumer Reviewer on panels that review research proposals and recommend funding decisions.

If you want to enlist in the war against prostate cancer and would like more information about the CDMRP, its Prostate Cancer Research Program, and the application process, go on-line to the CDMRP website at [http://cdmrp.army.mil/cwg](http://cdmrp.army.mil/cwg).

Be sure to tell the leader of your local prostate cancer advocacy group that you are interested in being a consumer reviewer. He should be aware of the CDMRP and be able to assist you with the application and nomination process. You may also obtain more information and a nomination packet by contacting:

Congressionally Directed Medical Research Programs
ATTN: Consumer Recruitment
1077 Patchel Street
Fort Detrick, MD 21702-5024

Telephone: (301) 619-7079
Fax: (301) 619-7792
E-mail: cdmrp.consumers@det.amedd.army.mil

If it was, it may be the last WRAMC Us TOO newsletter you receive! The newsletter is sent as First Class mail, so the US Postal Service forwards it to you at your new address for six months, then returns it to us as “Undeliverable.” The best way to provide timely change-of-address notification is to notify the editor directly. See page 2 for how to contact the editor.

♦ INSIDE THIS ISSUE ♦

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♦ FROM THE EDITOR’S DESK ♦

Readers in the Baltimore and Washington, DC, areas may be interested in attending a Urology Health Forum sponsored by the American Urological Association Foundation (AUA) on Saturday, November 18, 2006, at the AUA headquarters in Linthicum, MD. The topic is “Restoring Sexual Health.” The forum is free, but registration is required. See page 17 for details.

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Our program for the August 2, 2006, quarterly meeting featured Dr. Judd W. Moul, Duke University Medical Center, co-founder of our support group, and long-time supporter of our activities. We are very grateful to him for taking time from his responsibilities as Professor and Chief, Division of Urologic Surgery at Duke to be with us. A summary of his presentation, “Latest Developments in Prostate Cancer Research and Treatment,” begins on page 8.

♦

♦ PROGRAM FOR WEDNESDAY, NOVEMBER 1, 2006 ♦

Dr. Michael J. Manyak, F.A.C.S., is our speaker for November 1, 2006. He is the Vice President of Medical Affairs, Cytogen Corporation; Professor of Urology, Engineering, Microbiology, and Tropical Medicine at the George Washington University; and is associated with the DOD Center for Prostate Disease Research. Dr. Manyak has had an astonishing career which cannot begin to be described here. Just one example—he was the medical director for the salvage operation for the Titanic, and he dove to the wreckage site in a Russian submersible! His long experience and research in prostate cancer metastasis eminently qualifies him to present the topic, “Advances in Imaging for Prostate Cancer.” Join us at 7 PM on Wednesday, November 1, 2006, in Joel Auditorium. Plan now to attend and bring your spouse or a friend. They are always welcome.

DISCLAIMER: The materials contained in this newsletter are solely the individual opinions of the authors. They do not represent the views of any Department of Defense agencies. This newsletter is for informational purposes only, and should not be construed as providing health care recommendations for the individual reader. Consult with your physician before adopting any information contained herein for you personal health plan.
Ouch! That Hurts, and Still Six More To Go!
Good news from a recent regional meeting of the
American Urological Association in San Diego!
Investigators at the Mayo Clinic, Rochester, MN,
report that administering a topical anesthetic
several minutes prior to lidocaine injection at the
prostate apex and the surrounding rectal tissue
significantly reduces pain associated with the
prostatic biopsy. The prevailing procedure had
been to inject between the prostate base and the
seminal vesicles, but patients often complained
of pain. The study involved 243 men scheduled
for prostatic biopsy who reported pain levels on
a scale of 1-10. A topical anesthetic with 20%
benzocaine jelly was administered five minutes
before the injection of 1% lidocaine. Injection
sites were varied and 12 to 15 biopsy samples
were taken from each patient. Patients injected
in the prostate apex and the rectal wall reported
much less pain compared to other injection
locations. Overall, the procedures were well-
tolerated, with 84% of patients reporting a pain
score of 5 or less. The best pain control occurred
when the injection numbed the apex of the
prostate and some of the rectal wall. The
investigators said this method should become the
standard practice for prostate biopsies. (Source:
Reuters Health Information, September 18,
2006)

Alprostadil Cream and Erectile Dysfunction.
Two large studies of alprostadil cream (Alprox-
TD) show that the topical agent produces a small
but statistically significant improvement in
erectile function in many patients with mild-to-
severe dysfunction. The participants numbered
1,700 men with a mean age of 60. Twenty-one
percent were radical prostatectomy patients.
Scores for vaginal penetration and maintenance
of erection improved slightly but significantly.
Outcomes were dose-dependent and the overall
improvements were modest. The cream was
well-tolerated, with the most common adverse
effect being a burning sensation and redness at
the site of application. (Source: Urology 2006;
68:386-391, June 15, 2006, via Reuters Health,
September 6, 2006)

PSA After Treatment Predicts Survival in
Metastatic Prostate Cancer. PSA level after
androgen deprivation therapy predicts survival in
patients diagnosed with new stage D2
(metastatic) prostate cancer. Hussain, et al.,
University of Michigan, followed 1,395 men. At
the outset, 1,134 (81%) had a PSA level of 4.0
ng/ml or less, and 675 (48%) had an
undetectable PSA. Fewer patients maintained
these levels during the study period. For the 383
patients with a PSA greater than 4 ng/ml at the
study’s end, the median survival was 13 months,
compared with 44 months for the 360 patients
with a PSA between 0.2 ng/ml and 4.0 ng/ml,
and 75 months for the 602 patients with
undetectable PSA at months 6 and 7. Patients
with a PSA between 0.2 ng/ml and 4.0 ng/ml had
less than one-third the risk of death of those with
a PSA of more than 4.0 ng/ml. Furthermore, the
risk for patients with undetectable PSA levels
was less than one-fifth that of patients with a
PSA above 4.0 ng/ml. The researchers
concluded that a PSA of 4.0 ng/ml or less or an
undetectable PSA at the end of a 7-month
androgen deprivation therapy period is the most
powerful predictor of the risk of death in patients
with D2 (metastatic) prostate cancer. Men who
fail to respond to androgen deprivation by not
attaining a PSA of 4.0 ng/ml or less have
androgen independent disease and should be
referred to chemotherapy or novel systemic
therapies available in clinical trials. (Source: J
Clinical Oncology 2006;24: 3984-3990 via
Reuters Health Information, September 8, 2006)

External Radiation and Brachytherapy.
External beam radiation combined with low-
dose-rate brachytherapy significantly improves
biochemical control for patients with prostate
cancer. Jani, et al., University of Chicago,
compared survival rates for 189 patients treated
with brachytherapy and external beam radiation
(EBRT) compared to brachytherapy alone. After
Brachytherapy was selected as the primary therapy, adjuvant EBRT was added for patients with adverse prognostic factors. Fifty-four patients received supplemental EBRT 3 to 5 weeks before the brachytherapy. Patients were followed for two years, and biochemical failure was defined as two successive increases greater than 1 ng/ml in PSA levels. The combination therapy resulted in a significant biochemical control advantage compared to brachytherapy as a monotherapy. The 5-year biochemical failure-free rate was 80% for the combined therapy compared to 59% for the single modality. The researchers acknowledge that their findings differ from those of other studies. They note that most of those studies excluded high-risk patients. They agree that more study is required to determine the exact brachytherapy population that would benefit from the supplemental EBRT. (Source: *Urology*, 2006; 67: 1007-1011 via Reuters Health Information, June 27, 2006)

**Prostate Radiation Does Not Increase Rectal Cancer Risk.** There had been some suggestion that men who had radiation as their primary therapy for prostate cancer have an increased risk of developing rectal cancer. A Canadian study evaluated the records of 237,783 men who had prostate cancer. Of those men, 33,841 received radiation therapy, 167,607 had radical prostatectomies, and 36,335 received neither treatment. The researchers found that rectal cancer eventually developed in 243 men (0.7%) who received radiation; in 578 men (0.3%) treated with surgery; and in 227 men (0.8%) who were untreated. They found no evidence of significant increased risk for rectal cancer compared to the surgery patients or those men who went untreated. The study should reassure men that their decision to choose radiation therapy does not increase their risk of eventually developing rectal cancer. (Source: *Inter’l J of Radiation Oncology*, July 1, 2006, via the National Prostate Cancer Coalition, July 25, 2006)

**GI Toxicity Prolonged After Prostate Cancer Irradiation.** Giordano, et al., M. D. Anderson Cancer Center, University of Texas, say that gastrointestinal (GI) toxicity after external beam radiation therapy for prostate cancer may be more common than previously reported. The researchers studied 57,955 men 65 years of age or older. Of these, 24,130 had radiation therapy. After five years of follow-up, the GI diagnoses were 19.4% higher in patients who underwent radiation compared to those who did not. Hemorrhage was the most common adverse side effect; it was noted in 39.6% who had radiation therapy. In all, 4.4% of irradiated men were hospitalized with GI complaints. Increasing age, diabetes, and hormonal therapy were also associated with the apparent GI toxicity. The rates of GI toxicity were higher than those reported in earlier studies. The researchers conclude that the toxicities were rarely serious enough to require hospitalization, but they could negatively affect quality of life in prostate cancer survivors. (Source: *Cancer* 2006; 107: 423-432 via Reuters Health Information, July 26, 2006)

**VA Health Alert.** The Veterans Administration is contacting veterans in 11 states, the District of Columbia, and Puerto Rico who may have had a prostate biopsy with an improperly disinfected prostate biopsy transducer. The oversight has the remote possibility of exposing patients to Hepatitis B, Hepatitis C, or HIV. The VA is notifying men who received biopsies with the equipment in question at these VA facilities: District of Columbia; Iowa City, IA; Togus, Maine; Minneapolis, MN; Fort Harrison and Miles City, MT; Las Vegas, NV; Buffalo and Canandaigua, NY; Cincinnatti, OH; Oklahoma City, OK; Portland, OR; San Juan, PR; Memphis, Murfreesboro, and Nashville, TN; Milwaukee, WI. The contacted veterans will be offered appropriate testing. (Source: VA Press Release, May 2006 via the Us TOO “Hot Sheet,” August 2006)
**Bone Scans After Localized Prostate Cancer Therapy.** The PSA level at which to recommend a bone scan after treatment for early prostate cancer is controversial. A study by Warren, et al., Midwest Urology Foundation, Chicago, found that bone scans are not necessary in men with PSA levels less than 5 ng/ml following treatment for localized prostate cancer. Furthermore, the PSA level can increase to 20 ng/ml in men being treated with watchful waiting if caution is used. The researchers determined the incidence of bone metastases at varying PSA levels for 8,113 men treated with radical prostatectomy, radiation therapy, and watchful waiting. Over 10,000 bone scans were analyzed. For men treated with radiation or surgery, the incidence of positive bone scans was low (0.2% to 1.4%) when the PSA was below 5 ng/ml. For men treated with watchful waiting, the incidence of positive bone scans was also low (0.7% to 3.2%) when the PSA level was below 20 ng/ml. The researchers conclude that there are sufficient grounds to eliminate routine bone scans in patients with PSAs less than 5 ng/ml who have undergone radiation therapy and radical prostatectomy; in cases of watchful waiting or newly diagnosed disease, the need for routine bone scans can also be eliminated at a PSA level of less then 5 ng/ml, and with caution, this level can be increased to 20 ng/ml. (Source: J Urol 2006;176: 70-74 via Reuters Health Information, July 27, 2006)

**Lower PSA Threshold for African Americans.** A recent study shows that African American men with nonpalpable prostate cancer have greater tumor volume than white men with similar PSA levels. This suggests that the threshold for PSA should be lowered to 2.5 ng/ml for black men to increase the likelihood of finding cancers that are highly curable. This is especially true for African Americans less than 65 years old and otherwise healthy. Pettaway, et al., M. D. Anderson Cancer Center, University of Texas, found that black men had higher postoperative Gleason scores--a sign of tumor aggressiveness--than white men, despite having similar PSA levels and preoperative biopsy scores. The postoperative Gleason score was upgraded for 49% of African Americans, compared to 26% for white men. Also, specimens from African-American men had higher tumor volume, suggesting that even in black men with early American men had higher tumor volume, suggesting that even in black men with early stage disease, the opportunity for cure after surgery may be lower for them if the same PSA threshold for biopsy is used for all races. The researchers say the threshold PSA for biopsy for black men should be 2.5 ng/ml, and that black men should consider being screened at age 40. (Source: Cancer, July 1, 2006, via the National Prostate Cancer Coalition, August 15, 2006)

**Sex or Survival--This Is a Choice?** Patients with localized prostate cancer may choose between radical prostatectomy or radiation therapy. Although the topic is contentious, many urologists believe that surgery offers a higher survival rate; however, surgery may also produce a higher rate of sexual impotency compared to radiation. A recent study assessed how men value survival and sexual potency when asked to trade off one for the other. The study involved 50 men ages 45 to 70 years old who did not have prostate cancer. Given hypothetical rates of survival (90% at 5 years for surgery) and impotence (90% for surgery and 40% for radiation) 32% of respondents were unwilling to trade off any survival, but 68% were willing to trade off a 10% or greater advantage in survival (by choosing radiation) in order to maintain sexual potency. Willingness to trade off survival for sexual potency was significantly related to education level, but not to age, interest in sex, frequency of intercourse, or ability to achieve erection. The researchers concluded that some men may choose a therapy with lower long-term survival in order to increase their chance of remaining sexually potent. Such men may be difficult to identify in clinical practice, so physicians should thoroughly discuss both surgery and radiation in terms of their survival outcomes and their potential side effects, such as potency. (Source: Singer, et al., J Clinical
Family History and Prognosis. Some earlier studies had indicated that a man with a history of familial prostate cancer was at higher risk of having an aggressive cancer. That has now been challenged by Kupelian, et al., M. D. Anderson Cancer Center, Orlando. They studied the aggressiveness of familial versus sporadic prostate cancer in 4,112 men with stage T1-3 tumors. They found that early in the PSA era, a family history of prostate cancer was an independent predictor of biochemical failure. But later in the PSA era, men with a family history of prostate cancer presented sooner and with less aggressive disease. The researchers conclude that with the advent of improved PSA testing and technology, the impact of family history on prognosis has become minimal. (Source: *J Clinical Oncol* 2006;24:3445-3450 via Medscape, August 15, 2006)

Hemoglobin Drop Is a Poor Sign After Androgen-Deprivation Therapy. Researchers say that a sharp decline in hemoglobin levels three months after beginning androgen-deprivation therapy is associated with shortened survival and progression-free survival. Anemia is a recognized adverse effect of androgen-deprivation therapy, but little is known about the change in hemoglobin levels in anemic patients who are beginning treatment with the antiandrogen flutamide. Beer, et al., Oregon Health and Science University, followed 817 men, mean age 69.6 years, who were undergoing therapy with flutamide for metastatic prostate cancer. The group’s median hemoglobin level fell from 13.7 g/dl to 12.8 g/dl after three months. The reduction in hemoglobin was associated with shorter survival and progression-free survival. The researchers say their findings should not be construed as support for therapeutic correction of anemia because more research is required before specific recommendations can be made. (Source: *Cancer* 2006;107:489-496 via Reuters Health Information, August 8, 2006)

Free Drugs a Good Deal? Maybe Not. Some drug companies are promoting their products by offering coupons or free trial offers. For example, Pfizer, Inc., offers a free prescription of Viagra for every six filled, and Sanofi-Aventis offers a free seven-day supply of its sleeping pill Ambien. Consumer advocacy groups are concerned that coupons can spur a patient’s interest in taking a drug that may not be needed or not the best one for the patient. More than 10 million patients have redeemed free trial vouchers for drug products since 1994. Supporters of the free trial programs say they help cash-strapped patients who might otherwise delay therapy or skip a refill, and that prescriptions are necessary in order to participate. Opponents say these are drugs being offered, not shampoo The FDA earlier had expressed some concerns, but now it is reviewing its role in the coupon-free trial issue. (Source: Reuters Health Information, August 14, 2006)

PSA Testing and Finasteride. Finasteride is a drug prescribed for men whose prostates have become enlarged. It decreases prostate swelling and eases urination problems. However, the association of finasteride with high-grade tumors during the Prostate Cancer Prevention Trial (PCPT) prompted interest in exploring the phenomenon. Thompson, et al., University of Texas Health Center, studied the PSA test’s ability to detect prostate cancer in the PCPT in men taking finasteride or a placebo. They found that finasteride changed the diagnostic characteristics of the PSA test so that it detected prostate cancer with greater sensitivity and accuracy. They also suggest that the increased detection of high-grade prostate cancers in the finasteride arm of the PCPT may be related to the drug’s ability to improve the PSA test’s performance, and not to its induction of high-grade disease. (Source: *J of the National Cancer*
Institute, August 15, 2006, by Ariel Whitworth, via Aware, National Prostate Cancer Coalition, August 22, 2006)

PSA Predicts Treatment Success in Advanced Prostate Cancer. A new multicenter study showed that the PSA test predicted survival rates for men whose advanced prostate cancer was being treated with hormonal therapy. The study evaluated 1,345 men whose prostate cancer had spread to distant locations. After seven months of androgen-deprivation therapy, the researchers found that men whose PSA dropped below 4.0 ng/ml had only 25% risk of dying compared to men whose PSA was more than 4.0 ng/ml. The researchers say that a low or undetectable PSA after seven months of androgen-deprivation therapy is a powerful indicator of the risk of death in patients with new metastatic prostate cancer. Patients whose PSA was higher than 4.0 ng/ml survived for 13 months; patients whose PSA dropped below 4.0 ng/ml, but above 0.2 ng/ml lived 44 months; and men whose PSA was undetectable (below 0.2 ng/ml) lived 75 months. The study was conducted by the Southwest Oncology Group and led by researchers at the University of Michigan Comprehensive Cancer Center. The study is ongoing. Men newly diagnosed with metastatic prostate cancer and whose PSA level is at least 5.0 ng/ml should ask their urologist for a referral. (Source: J Clin Oncol, Vol 24, Issue 24, pp. 3984-3990, via the University of Michigan Health System, August 24, 2006, and AWARE, National Prostate Cancer Coalition, August 30, 2006)

Is Prostate Cancer Being Over-Treated? A recent study found that more than half the American men who had surgery or radiation for their prostate cancer might have been just as well off with watchful waiting. Since tumor progression can vary widely among patients, the idea is to offer treatment when it is clearly beneficial, and to avoid aggressive treatment with all its side effects when it is not. The study identified 71,602 men diagnosed with early prostate cancer who were classified into either high-risk or low-risk categories. More than half of the 24,835 low-risk men had undergone surgery or radiation therapy soon after diagnosis. Age appeared to influence treatment decisions. Men under age 55 were most likely to be treated with surgery instead of watchful waiting. Low-risk men over 70 were most likely to receive radiation therapy even though they had slow-growing tumors and would likely die of something other than their prostate cancer. Of course, the problem is how to establish whose prostate cancer is more aggressive. The researchers note that watchful waiting is not a permanent treatment choice, and that some men, particularly younger men, should eventually proceed to curative therapy, if and when their circumstances change. Although Gleason score is a major factor in the decision to treat, the patient’s attitude is also very important. Will a patient be comfortable living with a cancer diagnosis and be willing to participate in the required regular follow-ups? The researchers say their study does not claim to have the right answer, but rather, it shows the dimensions of the problem about when to treat. (Source: Reuters Health Information, August 15, 2006)
Introduction

It is really a pleasure to be back at Walter Reed to see so many old friends and sense again the ambiance of this great institution. I truly feel like I am back home again. Addressing tonight’s topic - *The Latest Developments in Prostate Cancer Research and Treatment* - is a tall order in a 45 minute presentation, so I am going to take a very eclectic approach. I will be presenting a series of headlines from both the popular media and professional journals to focus on broad trends, as I see them, that affect the diagnosis and treatment of the disease. As an aside, let me note that the traditional poster boys for prostate cancer awareness have been Senator Bob Dole, former Secretary of State Colin Powell, and General Norman Schwartzkoff - all of them treated here at Walter Reed, by the way. In my presentations when on active duty, I always used a slide at the outset showing them as an attention-getter. But now that I’m in North Carolina and NASCAR-land, I’ve had to become more “relevant,” so now I rely on Richard Petty as the prostate cancer poster boy!

The Dimensions of Prostate Cancer

If you do a Google search for the term prostate cancer, you get over 4 million “hits.” I know that most of you in this audience regularly use the Internet. Many patients consult the Internet before they actually consult a doctor. Patient education is a positive thing, but it can put pressure on health care providers as far as comprehensively counseling patients is concerned. Also, the widespread availability of information, not all of it timely or accurate, adds to the controversy about certain medical issues such as screening for prostate cancer. Prostate cancer medical professionals are expecting a surge of new cases in the near future. Last year there were about 232,000 cases reported, and there were about 30,000 deaths.

I tell you this to illustrate the fact that we may be on the verge of an even greater incidence of the disease due to demographic factors and societal trends. For example, this headline says that the so-called baby boomer generation is approaching its more mature stage in less than optimal health. The baby boomer generation refers to persons born between 1946 and 1964. This amounts to more than 75 million people in the United States. The oldest male boomers are now turning sixty this year and entering their peak years for possible prostate cancer diagnosis; and the youngest male boomers are turning forty-two and entering their peak years to consider initial prostate cancer screening.

I don’t know what the expected effect will be in the Washington, DC, metropolitan area, but I can tell you that in North Carolina we are expecting the annual rate of prostate cancer incidence to increase by 19% over the next five years. This situation is also influenced by
the continuing relocation of many out-of-state retirees to North Carolina.

So this is a major issue, and it is compounded by the fact that the national population is living longer. Let me illustrate that fact with this chart showing life expectancy in 2002. The average 60-year-old man in 2002 had a 20.2 year median life expectancy. This is the counseling dilemma. As many of these men are screened for prostate cancer, we will likely see many with early-stage disease that, in some cases, might not need aggressive treatment. On the other hand, we must recognize the potential impact of their longer life span. So we face a potential dilemma of either under-treating the patient or over-treating him.

Even more striking is that the average 75-year-old man in 2002 had a life expectancy of 10.3 years. That fact is especially important for urologists of my generation. During our training, it was the common wisdom not to offer the radical prostatectomy to men above age 75 because they were “too old” to benefit from that aggressive approach to therapy. Given the demographic information I’ve offered, we perhaps need to reexamine that approach. The last thing we need is to be accused of practicing age discrimination by under-treating men based largely on their age!

Now take a look at this headline, “Aging Population Creating Higher Demand for Surgery.” As you can see on this slide, the specialties of urology, ophthalmology, cardiothoracic surgery, general surgery, neurosurgery, and orthopedics expect increasing demand as the population lives longer and stays healthier. The urology specialty anticipates a 33% increase in demand for our surgical services by 2020 compared to today. Cancer diagnoses are likely to double for many of the other common cancers over the same time.

Now before I leave this topic, I want to talk about the potential “perfect storm.” You see this headline from USA Today saying “Medical Miscalculation Creates Doctor Shortage,” predicting that there will be a shortage of physicians. The urology specialty faces an even greater shortage. I’m worried because I am not so sure there will be someone to take care of me! I am right in the middle of that baby boom generation! Seriously, it is a source of concern; both the medical community and the government are realizing the challenge. Within 10 to 15 years there could be a serious shortage of health care providers at the same time we confront the baby boomers who are expected to live longer. Hence my reference to a “perfect storm.”

In addition to the increasing number of newly diagnosed men, you see this headline, “Cancer Survivors Need Better Care,” and that’s true. But why are we seeing it now? Well, it’s because we have so many more cancer survivors. Looking at the estimated number of cancer survivors in the United States from 1971 to 2000, we see a continuous rise. More and more people are beating cancer, surviving the disease.

Now for the challenge. Let’s take prostate cancer as an example. The good news is that we have a large number of prostate cancer survivors as represented by the men in this room. The bad news is that all those men need periodic follow-up, the quarterly check-ups, and all the procedures associated with them. Will we have the ability to perform those follow-ups if we get in the physician-shortage situation I have described? The urology community is already beginning to feel the shortage. I don’t have the solution, but I wanted to make you and the Us TOO group aware of it because advocacy is important. I hope that groups like Us TOO will start to
advocate for an adequate pool of health care providers; otherwise, prostate cancer care could be affected and some of the advances we have made could be diminished.

**PSA Screening**

Now this headline, “Study Emphasizes Value of Annual PSA Test.” I wanted to talk about this because one of the things that Us TOO has done so effectively is advocate for the PSA test. I think they are right on target--I have always felt that way. Let me refer to the 2005 update of the oft-cited Tyrolean Screening Study. This Austrian study is a classic in demonstrating the efficacy of the PSA. Austria is a socially and demographically stable country, ideal for large-scale medical research. The Austrian authorities conducted a nationwide screening test whereby the Tyrolean region had an active screening campaign and the remainder of the country did not. Looking at the data for 1988, 1991, 1994, 1997, 2000 and 2002, we see the incidence rates of prostate cancer detection in the Tyrolean region rose, and unsurprisingly so. But more interesting is what happened to the stages of prostate cancer. Look at the red line. It represents patients that were diagnosed with metastatic prostate cancer. What you are seeing is a dramatic decline in the rates of metastatic prostate cancer over time.

Obviously, the screening test resulted in more men being diagnosed with early-stage, more treatable disease, so the incidence of advanced stage disease sharply declined. That should translate into an eventual survival benefit, and sure enough, that is what occurred. This red line shows a plummeting rate of prostate cancer deaths beginning in about 1999, suggesting that the PSA was doing what it was supposed to do--saving lives of men with prostate cancer. I think this updated Tyrolean study is particularly important because it supports what Us TOO and other advocates have been saying all along --that PSA screening is important because it saves lives. Nevertheless, there are still influential naysayers who maintain that we should not be screening for prostate cancer because there is no conclusive scientific evidence that it saves lives without an elaborate randomized trial. They also find technical fault with the Tyrolean study. So the debate goes on. That is the reason I thought it important to share this update of the Tyrolean study with you.

**Statins**

There are a number of new research papers coming out. They are preliminary at this point, but they look helpful. They look at the statins (your Zocar, your Lipitors, your Crestors). If I asked for a show of hands tonight, I suspect about half the audience is on a statin. I know I am. At any rate, there has been some interesting data suggesting that statins may prevent prostate cancer or at least reduce its effect. Elizabeth Platz, a well-regarded scientist at Johns Hopkins, has done important work in this area. This is really an exciting area, and I would say to those who are on a statin to control cholesterol, it may also be helping your prostate cancer situation. I think all I can say here is that we need to say tuned.

**Obesity**

No doubt you are aware of the latest “hot topic” in the popular press--the issue of obesity and prostate cancer. Look at this headline, “Obesity-Prostate Cancer Link is Multi-Factorial and Complex.” The bottom line is that studies are addressing the role of obesity in the incidence of prostate cancer and the aggressiveness of the disease. The issue is
dramatically portrayed on this map of the United States. The darkest colors represent states that have the highest rates of obesity. For example in 1990, only Mississippi and West Virginia had more than 25% of their population considered to be obese. Now the obesity problem is much worse nationwide. Talk about another “perfect storm!” If we have an aging population, a shortage of health care providers, and now this obesity problem—well, you get my point! Now I don’t have the solution, but I find the obesity issue very disturbing, even if we subsequently learn that the link between obesity and prostate cancer is tenuous.

Even if it proves to have a minor impact on prostate cancer, obesity presents practical problems in treating patients. We are facing it in the clinics every day. The practical problems are not as great in treating a military population where there is a certain emphasis on physical conditioning, compared to the civilian population at large. I’ll tell you in the civilian world, especially in North Carolina, I see real problems. Just yesterday, I saw a patient who had an elevated PSA after surgery. I ordered an imaging procedure called a ProstaScint® to help detect the extent of metastasis, if any. But the patient weighed 375 lbs. and the equipment could not accommodate him. So here we were with the most sophisticated imaging technology available and unable to employ it effectively. We had to settle for a second-best alternative.

That is just one example. We regularly encounter situations that require two operating room tables to accommodate the patient. Not long ago, the fast food industry became defensive about its contribution to national obesity. There were even threats of class action suits against it. Healthier choices soon appeared on the menus. But the trend didn’t last long because the alternative food items just didn’t sell. Now we are hearing commercials for “quadruple burgers!”

**Body Mass Index**

What about the issue of body mass index and its relationship to prostate cancer? There have been a number of studies. Body mass index (BMI) is a ratio of height to weight in order to obtain a better scientific estimate of obesity. A BMI greater than 30 is considered obese. A BMI greater than 35 is considered morbidly obese.

The DOD Center for Prostate Disease Research here at Walter Reed was among the first to demonstrate that a high BMI (over 35) was associated with worse pathology after surgery and a higher chance of disease recurrence. Let me say that BMI is not yet clearly associated with prevalence, i.e., obesity doesn’t necessarily seem to increase the rate of prostate cancer. But this data does suggest that if you have prostate cancer and are obese, your prostate cancer may behave more aggressively. Obesity may also affect the PSA readings as was reported in an interesting study, “Higher Body Mass Index May Confound PSA Readings.” Obesity can decrease testosterone levels and increase estrogen levels. It is possible that this hormonal change can actually affect PSA levels. To add insult to injury, it is possible that obesity may even hurt our ability to detect prostate cancer.

**Nomograms**

Now let’s switch gears to consider this headline, “Nomograms Inserted into the NCCN and Prostate Cancer Guidelines.” NCCN stands for National Comprehensive Cancer Network, a group of major cancer centers that establish treatment guidelines for the different cancers. Many physicians rely on
NCCN guidelines to get better algorithms and protocols to treat cancer patients. Risk stratification is incorporated into the algorithms to place a patient into a risk category based on his PSA level, his Gleason score, and disease stage. I know Walter Reed has a very excellent multidisciplinary clinic and it considers risk stratification in evaluating patients for treatment. So the urologist and radiologist can sing off the same sheet of music, so to speak, when they are talking about individual patients and how to treat them. We do the same thing in our program at Duke.

**Time to Metastasis**

“PSA Measurements Predict Time to Metastasis”—another hot topic. The emphasis now is not what the PSA number is at any given time, but what the number is doing over time, i.e., PSA velocity or PSA doubling time.

A research paper published in the New England Journal of Medicine in late 2004 looked at men who had undergone radical prostatectomy. They basically found that if a man had a very rapid increase in his PSA in the year prior to his treatment, that fact seemed to predict a worse outcome. For example, a PSA velocity greater than 2 points in the year prior to treatment seemed to impact the prostate cancer-specific mortality.

I think the key teaching point here is that PSA change occurring over time is probably more important than the PSA number itself. This is particularly applicable if you are facing a disease recurrence and where you may not have had a completely undetectable PSA after surgery or radiation. In the past, doctors were likely to resume therapy based on some arbitrary PSA number; but now they are looking for these rates of change before advising about when to start secondary treatment.

The typical patient that I see is a 55 year-old man, healthy all of his life, but now has a PSA of 5 or 6 and a biopsy showing a Gleason 6 prostate cancer. So he has early stage prostate cancer. As many of you appreciate, he is faced with a treatment dilemma. Do I get it cut out? Do I get it radiated from the outside? Do I radiate it from the inside? Do I freeze it? Do I go on hormone therapy? The issue of watchful waiting is getting increased attention. Some recommend a new term—expectant management—because “watchful waiting” sounds like a passive approach and not an active monitoring approach. I still like to call it watchful waiting, but the point is that we can do a better job in offering this approach.

A nationwide study is getting under way called the START Protocol. It proposes to enroll about 1,500 patients randomized into a radical prostatectomy, external beam radiation, brachytherapy, or watchful waiting arms. In short, the men are randomized into an active therapy or active surveillance (watchful waiting) with selective intervention based on clinical progression. The latter group is monitored closely with periodic prostate biopsies and PSA tests, switching to active treatment only if there is some significant worsening of their condition.

Frankly, it will be interesting to see if men are willing to be randomized to this approach. I suspect that many men won’t be. It is difficult to let the computer, or the coin flip, make such an important decision for you. Would you?

A related Canadian study has been widely reported. Dr. Klotz in Toronto has a single-center study where he enrolled about 300 carefully selected men in a watchful waiting
protocol. Looking at the results after eight years, the overall survival rate is 85%. You may be thinking “Oh my goodness, 15% of the men died.” But if you look at the actual prostate cancer survival, it was 99% after eight years. In other words, there were only two prostate cancer-related deaths; almost all the other deaths were from other causes. Some observers may say that the study included patients who obviously had other health conditions that they eventually died from. But think of it--99% cancer-specific survival after eight years! This is hard to beat by any primary treatment. It boils down to careful patient selection. My opinion is that watchful waiting is a viable alternative for patients who are very carefully selected for it.

Now let’s look on the other side of the coin. There are two related studies I want to describe. One using the CPDR database here at Walter Reed was published a couple of years ago. It included some Walter Reed patients as well as military patients from other major military treatment centers. All the men were younger than 70 with low risk, localized prostate cancer, and they all began a watchful waiting regimen. Let me emphasize that this was on an ad hoc basis by many different doctors at several different locations and at different times.

Unlike the Canadian study that had control protocols and where the patients were very carefully selected, the only linking mechanism in the CPDR study was that the patients were treated in the military healthcare system; so the study itself was not done under formal protocol conditions. Only 27% of these 313 men remained on watchful waiting at the four-year point. So you could argue that watchful waiting is a questionable approach because about three-quarters of the patients “failed” watchful waiting and had to resort to a primary therapy. Looking at it another way, one could say, “Well, you had many men that were able to delay for several years the side effects often associated with the primary therapies. Alternatively, you can interpret it, “Wait, those men had to endure considerable psychological stress while living with a prostate cancer diagnosis for those years, and almost three-quarters of them ended up having a primary therapy anyway.”

In short, the urology community recognizes that it needs to refine this approach, yet we are unsure how to proceed. We know we need to do more definitive studies, but we are not sure we can get the patients to buy into randomized studies. So this is where we stand with watchful waiting.

**PSA Recurrence**

Now I want to talk briefly about PSA-only recurrence. I know that there are men in the room tonight who have experienced it. Perhaps you had a primary therapy, but eventually your PSA started to creep up again. The hot news in the last year is that we are doing a better job of risk stratification for PSA recurrence. It simply recognizes that in men with a rising PSA after surgery or radiation, the disease doesn’t act the same. There is a variety of ways that it may behave and it is based on how quickly the PSA is rising as measured by PSA doubling time.

When the PSA recurrence occurred, did it happen very soon after the surgery or radiation, meaning a couple of years, or did it happen later? Later is better than earlier. What was the Gleason score in the men who had surgery? In one study, the men were all radical prostatectomy patients. One group had a rapid PSA doubling time--doubling every three months or even every three to eight months. Men in this group tended to have a worse outcome compared to the other groupings.
The key teaching point for men with rising PSAs after primary therapy is that you and your doctor must closely monitor your PSA. Your doctor may not want to start additional treatment right away and he probably should not. You need to be patient long enough to determine what your PSA doubling time is. This is very difficult for some patients. They know their PSA is going up, and they want something done ASAP. Yet it is crucial to wait long enough to get a handle on this doubling time before turning to hormonal therapy or some other treatment. Hormonal therapy is important, but it is better to tailor it to the patients who will truly benefit from it.

Now the final two slides on the PSA recurrence topic. This was a research paper that I was proud to be associated with at Walter Reed before I retired. It had an impact, yet there is still much to be done in this area. We were looking at men who had a rise in PSA after surgery, and we considered the outcomes of men who started hormone treatment fairly early after recurrence, compared to men who waited longer. When I say “early hormone treatment,” I mean that the hormonal treatment was based on the patients’ PSA levels when they started on hormones. It’s not a point in time; rather, it is based on the PSA level. For example, you and your doctor decide on a course of hormone therapy before your rising PSA goes above 5.0. Another patient and doctor may decide to begin hormone therapy after the PSA exceeds 5.0, perhaps to avoid side effects.

The study’s bottom line was that among the high-risk men (postoperative Gleason score greater than seven or a PSA doubling time less than a year), those who started the hormone therapy earlier seemed to do better. They appeared to enjoy a longer cancer-free outcome than those who started hormonal therapy later. The only downside to the paper is that our follow-up was too short to provide the ultimate outcome. My conclusion is that we need to do a longer follow-up to see if the results have stayed the same or changed.

**Osteoporosis**

Let me return to the aging population topic again. Look at this headline, “Better Osteoporosis Management a Priority, Impact Predicted to Soar with Aging Population.” Osteoporosis is an issue with men too, not just women. At last we men are realizing that we are also at risk for osteoporosis, just like that “little old lady” we always sympathized with! I am trying to determine at what age I am going to start Vitamin D and calcium replacement for myself.

Consider these statistics. The rate of bone loss in men after age 35 is 0.5 to 1% per year and that’s in healthy men. If we look at men on hormonal therapy for prostate cancer, the bone loss is 1.4 to 2.6% per year, much higher than age-match control group. It works out that a man on hormones has bone loss 6 to 17% greater than a man who is not on hormones. The rates of fracture are even higher.

The classic study is the Daniel Paper published in the Journal of Urology in 1997. The men studied had an orchiectomy (surgical removal of the testicles) which was the traditional hormonal therapy prior to Lupron. They had a higher rate of fracture. This wasn’t just the common clinical fracture; this was also the lumbar spine fractures, when a CAT scan or X-ray would show compression of the spine. That counted as a fracture, too. It’s not like a long-bone fracture in a leg or arm, but it is a fracture. So how do we deal with this?
Here at Walter Reed they have a great protocol. Virtually everyone who is on long-term hormonal therapy is counseled about Vitamin D and calcium replacement therapy. The protocol is very aggressive in offering bisphosphonates for these men who are at risk for osteoporosis. Bisphosphonates are chemicals that work on the skeletal system to help prevent bone loss. The one that I highlight is called zolendronic acid, also known as Zometa, an FDA-approved drug to treat men with prostate cancer. Some people in this room may be on this drug. It is the only one that is FDA-approved for men at risk for osteoporosis who are on hormonal therapy for prostate cancer. One concern is the very slight risk of something called osteonecrosis of the jaw, a condition usually related to poor dental health. We always ask patients to see their dentists for a comprehensive dental examination before starting on the drug. In general, people with good mouth and dental health are not at risk.

I am going to stop here and take your questions. Again, I am grateful for the opportunity to be with you. Thank you for inviting me back.

Questions and Answers

**Question** – Regarding the ultra-sensitive PSA test, is it appropriate for those of us who have had primary treatment, such as an RP, but with no evidence of recurrence?

**Answer** – For those who are not familiar with the ultra-sensitive PSA test, let me say that there are basically two methods that laboratories employ to measure PSA. The one you are likely familiar with is the standard PSA test which measures down to about 0.1 ng/ml. Then there is the ultra-sensitive PSA test which provides readings down to 0.001 ng/ml. The American Urological Association (AUA) has been conducting an exhaustive literature search which considers this issue. Their report will be released soon. In general, it will say that the scientific literature does not support anything less than 0.2 ng/ml. Any value below a 0.2 ng/ml is at the noise level, meaning that treatment decisions should not be based solely on a PSA less than 0.2 ng/ml. Of course, this applies to surgery patients. The AUA will cite 2.0 ng/ml as the new consensus definition of recurrence. So the standard PSA test is acceptable for men in your situation.

**Question** – Regarding PSA doubling time, is an increase of 0.3 to 0.6 ng/ml as important as 3.0 to 6.0 ng/ml? When does the absolute value have meaning regarding doubling time?

**Answer** – PSA doubling time is based on a logarithmic transformation of PSA. It’s not based on a straight line. I would be very hesitant to put too much weight on those lower numbers. You don’t want men saying, “Oh, my gosh, my PSA went from 0.3 to 0.6 ng/ml and my PSA doubling time is three months. I am going to be dead in five years.” Prognosis should be based on PSA testing over a longer period of time with multiple PSA doubling time measurements in order to predict the survival outcome. There is still much uncertainty in this area.

**Question** – Based on a chart you showed, it seemed the indication was for men who had Gleason scores larger that 8 with doubling times that were rather short. Was there also a curve for men who had short doubling times, but whose Gleason scores were less than eight?

**Answer** – Great question. You were referring to the early versus late decisions for hormonal therapy. That paper was based on about 1,300
men who had surgery and then had a PSA recurrence. Looking at the entire group of 1,300 men whose risk stratification ranged from low to high, we could not demonstrate that early versus late hormonal therapy made a difference in outcome. But there was a benefit from an early hormonal therapy decision for the high risk category, i.e., men who had a worse Gleason score and faster PSA doubling time. It’s a function of the length of follow-up. With a longer follow-up, we might have found more benefit.

**Question** – A friend of mine went to Canada to get an ultrasound treatment for prostate cancer. Would you comment on it?

**Answer** – The question is referring to high-intensity focused ultrasound. Last May at Duke we performed the first high-intensity focused ultrasound treatment for prostate cancer in the United States. At this point the procedure is still investigational in nature because it is not FDA-approved at this time. The system uses a transrectal probe that delivers ultrasound to ablate prostate tissue. It is another way to ablate prostate cancer without removing the prostate.

The $64,000 question is whether it will prove as effective as radical prostatectomy or radiation. It is still very early in the game. The experience to date in Europe has been promising with some claims that it is at least as effective as radiation or cryotherapy. The problem is that it is dependent on how well the prostate gland can be imaged and how willing one is to believe that a therapy involving the non-removal of the prostate gets rid of all the prostate cancer cells. With more and more men within their 30s, 40s and early 50s being diagnosed, the failure to completely ablate the disease means that down the road many of these younger men may face recurrence.

All these matters are going to be controversial compared to what I still consider the gold standard, a well-done nerve-sparing radical prostatectomy that cures, restores full urinary control, and retains most, if not all, of the sexual function. That is still the gold standard and it’s a high bar to reach.

**Question** – Has there been a difference in the point at which mortality likely occurs after the onset of hormone therapy?

**Answer** – I am glad you brought that up. If you rely too much on the Internet and read uncritically, you could be misled. For example, you may read that after you begin hormonal therapy, the end is in sight in two or three years or so. That “information” is way out of date and likely based on men who probably had rip-roaring bone metastases upon diagnosis. Yes, in that earlier era before wide-spread screening, many men presented with advanced disease. And yes, they would commence hormonal therapy, but it often was very late. So they likely had only two to five years of survival before dying of prostate cancer. But now when we consider starting hormone therapy when the PSA is 0.4 ng/ml or even 1.0 ng/ml, and when there is time to establish the PSA doubling time, then those two to five years survival predictions don’t apply at all.
The WRAMC Us TOO Prostate Cancer Support Group holds quarterly and monthly meetings.

QUARTERLY MEETINGS

Meeting with a Speaker:  First Wednesday of  February, May, August, November
Time:  7:00 -  8:30 PM

Location:  Joel Auditorium  (second floor of main hospital building)

Leading medical professionals present selected current topics to the support group

MONTHLY MEETINGS (2)

Second Wednesday of every month in two sessions

   Day time session:   1:30 - 3:00 PM

   Evening session:     6:30 - 8:00 PM

Both meetings are in the conference room of the Center for Prostate Disease Research, fifth floor (Ward 56) in the main hospital building.

The monthly meetings are informal discussion groups treating topics of interest to attendees.

THE AMERICAN UROLOGICAL ASSOCIATION
PRESENTS
A UROLOGY HEALTH FORUM

“RESTORING SEXUAL HEALTH”

WHEN:  Saturday, November 18, 2006 - 12:30 to 4:00 PM

WHERE:  American Urological Association Headquarters
Attendance: The Forum is FREE, but you must register in advance. To register, call AUA at 1-800-908-9414 or online at www.urologyhealth.org.

TOPICS

Incidence and Prevalence of Sexual Dysfunction
Types of Dysfunction - Male and Female
Common Health Conditions Affecting Sexual Function
Post-Menopausal Sexuality - An Oxymoron?
Treatment Options - Today and Tomorrow
Controversies in Sexual Dysfunction - Diagnosis and Treatments
and
A Sexuality in History Presentation

GETTING THERE:

From Baltimore: Take MD-295 South. Take West Nursery Road exit. Go to the light at the end of the ramp and turn left. Go to the second light and turn left on Corporate Boulevard. AUA Headquarters is straight ahead.

From Washington, DC: Take MD-295 North. Take the West Nursery Road exit. Go to the light at the end of the ramp and turn right. At the next light, turn left on Corporate Boulevard. AUA Headquarters is straight ahead.

◆ WRAMC US TOO COUNSELORS ◆ (AS OF OCTOBER 6, 2006)
(These persons are willing to share their experiences with you. Feel free to call them.)

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MEETING ANNOUNCEMENT

WEDNESDAY, NOVEMBER 1, 2006
7 PM
JOEL AUDITORIUM (SECOND FLOOR)
WALTER REED ARMY MEDICAL CENTER

SPEAKER

MICHAEL J. MANYAK, M.D., F.A.C.S.
Vice President of Medical Affairs, Cytogen Corporation
Professor of Urology, Engineering, Microbiology, and Tropical Medicine at
The George Washington University

TOPIC

“ADVANCES IN IMAGING FOR PROSTATE CANCER”