

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

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◆ **Department of Defense Prostate Cancer Research Program** ◆

The FY14 Defense Appropriations Act provides \$80 million to the Department of Defense Prostate Cancer Research Program (PCRP) to support innovative, high-impact prostate cancer research. This program is administered by the US Army Medical Research and Materiel Command (USAMRMC) through the office of the Congressionally Directed Medical Research Programs (CDMRP).

The PCRP's FY14 mission is to find and fund research that will lead to the elimination of death from prostate cancer and enhance the well-being of men experiencing the impact of the disease. As such, the PCRP seeks to focus applications and direct funding by providing the following Overarching Challenges and Focus Areas to address critical needs in prostate cancer research and clinical management.

Research applicants are strongly encouraged to propose research that addresses the Overarching Challenges and Focus Areas.

Overarching Challenges: (1) Develop better tools for early detection of clinically relevant disease; (2) Distinguish aggressive from indolent disease in men newly diagnosed with prostate cancer; (3) Develop effective treatments and address mechanisms of resistance for men with high-risk or metastatic prostate cancer; (4) Develop strategies to optimize physical and mental health of men with prostate cancer.

Focus Areas: (1) Biomarker Development; (2) Genetics; (3) Imaging; (4) Mechanisms of Resistance; (5) Survivorship and Palliative Care; (6) Therapy; and (7) Tumor and Microenvironment Biology.

Visit <http://cdmrp.army.mil/pcrp/> for more information about the research effort and how you can participate.

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◆ **FROM THE EDITOR** ◆

Our support group is a chapter of Us TOO, International, the largest prostate cancer advocacy organization. Have you visited the Us TOO website yet? Try it, you will like it! It contains a wealth of information such as current developments in prostate cancer therapies. And it's monthly *Hot Sheet* is a must-read publication. Go to www.ustoo.org to see what you have been missing.

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◆ **SPEAKER'S REMARKS - FEBRUARY 6, 2014** ◆

Our program featured Dr. Michele Ojemuyiwa, Department of Urology, Walter Reed National Military Medical Center. Her topic was "Hormone Therapy 101," a review of what every man affected by prostate cancer should know about hormone therapy. A summary of her presentation begins on page 12.

◆ **MEETING SCHEDULE FOR MAY 29, 2014** ◆

Our program for Thursday, May 29, is a joint presentation by Dr. James David, a board certified psychotherapist now in private practice, and Dr. Peter Fagan, Associate Professor of Medical Psychology in the Department of Psychiatry and Behavior Sciences, The Johns Hopkins University School of Medicine. Dr. David is a retired Army officer who led the U.S. Army's Family Support Center Program with 165 locations world-wide and was chief operating officer of a clinical service in a major medical center. **Their topic is: "Life with Cancer: Practical Tools for Living with Uncertainty."**

Join us at 7 PM, Thursday, May 29, 2014. Your family members and friends are always welcome. There is no charge and no registration is required. (The presentation also may be viewed live by video teleconference at the Fort Belvoir Community Hospital. Go to the Oaks Pavilion, 1st floor, Room 332 to participate.)

**SEE THE BACK PAGE OF THIS NEWSLETTER FOR
IMPORTANT INFORMATION ABOUT THIS MEETING.**

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PROSTATE-SPECIFIC ISSUES

Six Months Hormone Therapy Plus Radiation Therapy Improves Prostate Cancer Survival. Men with prostate cancer that is small and confined to the prostate gland but at risk of growing and spreading, do better if they are treated with radiotherapy combined with androgen deprivation therapy (ADT), which lowers their testosterone levels. These research findings were presented at the 33rd conference of the European Society for Radiotherapy and Oncology (ESTRO33) in Vienna, Austria.

Bolla, et al., Grenoble University Hospital, France, agreed that longer follow-up is necessary to assess the impact on these men's overall survival. Nevertheless, these findings need to be taken into account in daily clinical practice. The researchers emphasized that three-dimensional conformal radiotherapy, whether intensity-modulated or not, and regardless of the dose level, has to be combined with short-term androgen deprivation therapy in order to obtain a significant decrease in the risk of relapse.

The trial results indicate that this combined treatment approach should be an option proposed for men with localized prostate cancer that has an intermediate or high risk of growing and spreading.

The trial involved 37 centers in 14 countries and 819 men. The patients had early stage prostate tumors, as confirmed by analyses of biopsy samples and levels of prostate specific antigen (PSA), that were at intermediate or high risk of growing and spreading to other parts of the body. The patients were randomized to receive either radiotherapy alone or radiotherapy and two subcutaneous injections of luteinizing hormone-releasing hormone analogues (LH-RH analogues), which lowers levels of testosterone to cause reversible chemical castration.

The men were followed for an average of 7.2 years. Regardless of the radiotherapy dose and whether it was intensity modulated, the 403 men who received radiotherapy combined with hormone treatment were significantly less likely to have suffered a relapse and progression of their cancer than the 407 men who were treated with radiotherapy alone. (Source: OncologyNurseAdvisor: May 6, 2014)

Quarter of Prostate Cancer Patients May Abandon 'Watchful Waiting' Approach.

Doctors may recommend no treatment at all when a man is diagnosed with prostate cancer, opting instead to keep a close eye on the slow-growing tumor and acting only when it becomes aggressive. But a new European study tracked how many men came back for regular checkups over 13 years. It found that "active surveillance" has a major flaw -- if men don't come back for regular checkups, doctors won't be able to tell if or when their prostate cancer becomes life-threatening.

A quarter of prostate cancer patients participating in a Swiss active surveillance study didn't bother showing up for their recommended appointments, according to the study reported at the annual meeting of the European Association of Urology in Stockholm.

Active surveillance -- also known as "watchful waiting" -- is a pragmatic treatment strategy derived from two known facts about prostate cancer. First, prostate cancer grows so slowly in most men that they are likely to die from other causes. Second, the surgery and radiation therapy used to treat prostate cancer often cause impotence, incontinence and other side effects that affect the man's quality of life. Prostate cancer is the most common cancer in American men other than skin cancer, but

the 15-year survival rate for prostate cancer is an impressive 94 percent. As a result, many doctors have concluded it's better to leave the prostate cancer alone and only act if it accelerates.

This new study followed 157 men during 13 years of active surveillance and found that after 13 years, about 28 percent of all patients required treatment because their prostate cancer flared up. Nearly all the men were cured of their prostate cancer, with an overall group survival rate of 94 percent. However, another 27 percent of the men in the study didn't bother coming back for check-ups after being placed on active surveillance, leaving themselves potentially vulnerable to a prostate cancer flare-up. Researchers also found that about 19 percent of the men refused to undergo a second biopsy three months after their diagnosis, to confirm the results of their first prostate cancer biopsy.

The study highlights the need for doctors to impress upon prostate cancer patients the importance of checkups. Compliance from the patient throughout the whole process is a must, as watchful waiting can lead to undetected metastasis and spread to other organs.

Dropout rates are probably even worse in the United States than in Switzerland, said Dr. Otis Brawley, chief medical officer for the American Cancer Society. Prostate cancer patients also might put their condition on the back burner because they are facing other, more critical medical issues, or just don't want to hassle with invasive probes on a regular basis, he said. On the other hand, Dr. Brawley saw this new study as a success story for active surveillance, in that three-fourths of the men who kept their appointments never needed treatment.

Because this study was presented at a medical meeting, the data and conclusions should be viewed as preliminary until published in a peer-reviewed journal. (Source:

European Association of Urology, news release, April 10, 2014 via HealthDay, MedlinePlus, National Institutes of Health, April 21, 2014)

Low Vitamin D Linked to Aggressive, Advanced Prostate Cancer. Low blood levels of vitamin D may be linked to more aggressive and advanced cases of prostate cancer in men, a new study suggests. And black men with low vitamin D levels were more likely than those with normal levels to test positive for cancer after a prostate biopsy.

The study, published May 1 in the journal *Clinical Cancer Research*, suggests that vitamin D may play an important role in how prostate cancer starts and spreads, although it does not prove a cause-and-effect relationship. Researchers aren't yet sure exactly how it comes into play or even if taking extra vitamin D might keep prostate cancer in check.

"There are still many questions about this relationship that have to be answered," said Dr. Len Lichtenfeld, deputy chief medical officer at the American Cancer Society who was not involved in the research. "We really don't know, for certain, what role vitamin D plays in cancer -- either the genesis or beginning of cancer -- or in defining how aggressive the cancer may be," he said. "Further research has to be done."

What is known is that vitamin D plays several critical roles in how cells develop and grow. "It seems to regulate normal differentiation of cells as they change from stem cells to adult cells. And it regulates the growth rate of normal cells and cancer cells," said study author Dr. Adam Murphy, Northwestern University's Feinberg School of Medicine in Chicago.

Vitamin D is also known as the "sunshine vitamin" because skin makes it when exposed to sunlight. Vitamin D levels tend to drop with advancing age, and deficiency is

more common in seasons and regions that get less sunlight and in people with darker skin, which naturally blocks the sun.

What about the vitamin's possible relationship to cancer? "When you squirt vitamin D on prostate cells in a petri dish, their rate of growth slows down," Murphy said. The idea is that too little of this critical vitamin in the body may cause cell growth to go awry, leading to cancer.

To test that idea, researchers checked vitamin D levels in 667 Chicago men between the ages of 40 and 79 who were having prostate biopsies because they'd recently had an abnormal PSA test or because a doctor felt changes to the prostate during a physical exam.

Normal vitamin D levels are in the range of 30 to 80 nanograms per milliliter (ng/ml). Vitamin D deficiency, or a level under 20 ng/ml, was relatively common among all the men tested. About 44 percent of the men with positive biopsies and 38 percent of those who tested negative for cancer had low vitamin D levels. Among men who tested positive for cancer after their biopsies, those who also had very low levels of vitamin D -- under 12 ng/ml -- had greater odds of more advanced and aggressive cancers than those with normal levels.

The connection between vitamin D and cancer seemed to be even stronger in black men. Black men with vitamin D levels under 12 ng/ml were far more likely than those with normal levels to test positive for prostate cancer in the first place. In general, black men are also more likely to be diagnosed with prostate cancer. On average, men have about a one-in-seven lifetime risk of getting prostate cancer. That risk rises to one in five for black men, according to the U.S. Centers for Disease Control and Prevention.

Researchers aren't sure whether lower vitamin D levels may help to explain why

black men are at higher risk for prostate cancer. They say longer and larger studies are needed to sort out the connection. (Source: American Cancer Society; May 1, 2014, *Clinical Cancer Research* via HealthDay News, May 1, 2014, National Institutes of Health)

Longest Prostate Cancer Active Surveillance Study Promising.

The longest follow-up to date of active surveillance in patients with favorable or intermediate-risk prostate cancer shows that it is a safe and feasible approach for as long as 20 years after diagnosis.

Men in the study cohort had early-stage disease and were managed with surveillance; they were treated only if there were signs of disease progression. Up to 20 years after diagnosis, 1.5% of the 993 men had died, and 3.1% had developed metastatic disease. In addition, death was 10 times more likely from other causes than from prostate cancer, reported Laurie Klotz, MD, from the Sunnybrook Research Institute in Toronto.

"This is the longest, most mature follow-up with the explicit strategy of conservative management and selective delayed intervention," he told *Medscape Medical News*. "Even at 15 to 20 years, the prostate cancer mortality rate is really very low, you've avoided treatment in the majority of patients, and even the ones treated late still had a long period of normal quality of life before they had treatment." The results were reported at the European Association of Urology, 29th Annual Congress.

At 5, 10, 15, and 20 years after diagnosis, 75.7%, 63.5%, 55.0%, and 55.0% of patients, respectively, remain untreated and on active surveillance. During the follow-up period, 15 died from prostate cancer and 7 developed metastatic disease.

The prospective single-group cohort study enrolled men (median age, 69 years) with

confirmed prostate adenocarcinoma who had undergone no previous treatment. Definitive intervention was offered to patients if they had a prostate-specific antigen (PSA) doubling time of less than 3 years, Gleason score progression (to 4 + 3 or greater), or unequivocal evidence (including MRI) of clinical progression. The remaining 993 patients were followed with active surveillance.

In an earlier follow-up of the patients, at a median of 6.8 years after enrollment, only 5 subjects had died of prostate cancer — all of them fairly early into their surveillance. In all 5, it looked like their disease "wasn't preventable with earlier treatment," said Dr. Klotz. In the latest analysis, median follow-up is 8.1 years. "But now it's slightly more sobering. We're starting to see some deaths in patients who have actually developed their metastases late. Perhaps if they'd been treated a decade before, they might have been cured."

Dr. Matthew Cooperberg, MPH, at the University of California, San Francisco, observed: "The question is how many men died of prostate cancer because they went on active surveillance instead of getting immediate treatment. The answer to that question is always going to be greater than 0," Dr. Cooperberg explained. "However, we all think that it's very, very, very low; it's far lower, most likely, than the number of men who are harmed or potentially harmed from overtreatment for low-risk disease."

At this stage, active surveillance "is a treatment approach in evolution," said Dr. Klotz. Research continues into how to refine the parameters for triggering intervention.

"We've shifted to a more MRI-based evaluation of patients, which I think in the long run is going to change the shape of the time-to-treatment curve," he said. "When something doesn't seem right — either a patient has a short [PSA] doubling time or

some small amount of Gleason pattern 4 — we now go to MRI. Previously, we treated them." (Source: European Association of Urology's 29th Annual Congress: Abstract 26. Presented April 12, 2014; via Medscape Medical News, April 14, 2014)

Study Sees Little Value in Taking Cialis During Radiation Treatment. Taking the erectile dysfunction drug Cialis while receiving radiation therapy for prostate cancer doesn't seem to help men's sexual function after treatment, a new study finds.

Researchers from the Mayo Clinic and colleagues across the United States and Canada have found that Cialis does not help men avoid erectile dysfunction after radiation therapy for prostate cancer. Erection problems are common in men who have been treated for prostate cancer, and the rates reported in the medical literature vary widely. According to background information in the study published in the April 2 issue of the *Journal of the American Medical Association*, about 40% of men report erectile dysfunction after radiation therapy.

One way that radiation affects erections is by damaging the arteries that carry blood to the penis. As the treated area heals, the blood vessels lose their ability to stretch due to scar tissue in and around the vessels. They can no longer expand as much as is necessary to let in enough blood for an erection. Radiation may also affect the nerves that control a man's ability to have an erection.

Cialis is a pill that works by increasing blood to flow to the penis. It is sometimes prescribed to men with erectile dysfunction after radiation treatment, but the researchers wanted to find out whether taking Cialis once a day could prevent erectile dysfunction from occurring if it was begun when radiation started.

They randomly assigned 242 patients with early stage prostate cancer to receive daily doses of Cialis or a placebo. The men started the drug within a week of starting radiation and continued for 24 weeks. They found that between 28 and 30 weeks after the start of radiation therapy, 79% of those taking Cialis were able to maintain erectile function compared with 74% of those taking the placebo – not a significant difference. After a year, 72% of men who took Cialis and 71% of those who took the placebo were able to maintain an erection. Overall, Cialis was not associated with improvement in overall sexual function and the partners of men who took Cialis in the study did not report a significant effect on sexual satisfaction.

The authors concluded that taking Cialis every day does not prevent erectile dysfunction in prostate cancer patients being treated with radiation, and other strategies should be explored. This may include different dosing, further refinements of radiation delivery methods, and other treatments that are available to help with erection problems. (Source: *Journal of the American Medical Association*, April 2, 2014 via HealthDay News April 1, 2014, and MedlinePlus, National Institutes of Health)

Testosterone and Cardiac Risk. A large new study found that prescription testosterone raised the risk of heart attacks in older men and in middle-aged men with a history of heart disease, prompting some experts to call for more extensive warning labels on the drugs.

The new study is one of several in recent years that have highlighted cardiac problems as a potential side effect of testosterone gels, patches, pellets and injections. The hormone is approved for low testosterone levels and is widely marketed for symptoms of “low T,” including fatigue, low libido and loss of energy. Sales in the last decade have soared.

By itself, the new study, which was not a randomized trial, the gold standard in medical research, “may not tell us very much,” said Dr. Michael Lauer, the director of cardiovascular sciences at the National Heart, Lung and Blood Institute, who was not involved in the study. “But when you put this together with the rest of the medical literature, this tells us that we potentially have a problem.”

The drugs carry no mention of an increased risk on their labels or in their advertising materials, said Dr. Sidney M. Wolfe, a senior adviser to the Washington advocacy group Public Citizen. “Given that there have been several studies now, I don’t see how the Food and Drug Administration can justify having no warnings of heart attacks at all,” he said.

In a statement, Andrea Fischer, an FDA spokeswoman, said the agency was reviewing the new findings. “We will communicate any new safety information on testosterone products when our reviews of all new information have been completed,” she said.

The new study, published on Wednesday in the journal PLoS ONE and funded by the National Institutes of Health, tracked about 56,000 older and middle-aged men around the country who were prescribed testosterone between 2008 and 2010. The study looked specifically at their rate of heart attacks in the year before receiving their new prescriptions, and in the three months after.

Men 65 and older had double the rate of heart attacks in the months after starting the drug, as did those younger than 65 with a previous diagnosis of heart disease. There was no evidence of greater risk in the younger men without a history of heart problems.

One question surrounding testosterone is whether any potential increase in cardiac risk is caused directly by the drug, or by its

impact on behavior. Testosterone boosts libido, for example, which may spur older men to engage in strenuous sexual activity.

The new study sought to address this question by comparing the men using testosterone to a separate group of 170,000 older and middle-aged men who filled prescriptions for Viagra and Cialis. Those men did not experience more heart attacks. The new research was led by a team at the National Cancer Institute, the University of California, Los Angeles, and Consolidated Research, an independent research firm specializing in epidemiology.

In November, a study in *The Journal of the American Medical Association* found that older men, many with a history of heart disease, had a nearly 30 percent increase in mortality, heart attacks and stroke after using testosterone. And in 2009, a federally financed, randomized study that was intended to test whether testosterone gel could help elderly men build muscle and strength was halted early because of heart attacks and other cardiac problems in men using the drug.

Testosterone increases the production of red blood cells, which can clump together or coagulate, essentially making blood thicker, said Mary Schooling, a professor of public health at Hunter College who published a large study linking testosterone use to cardiovascular events last year. That may be especially hazardous in men who have narrowed arteries because of aging and disease. "There is a potential for harm, and people should know about this," she said.

Although testosterone levels naturally decline with age, testosterone therapy is approved for use only in men with hypogonadism, an underlying endocrine disorder that typically results in a severe testosterone deficiency. Making that diagnosis requires doing a blood test. But studies show that nearly a quarter of men pre-

scribed the drug do not have their levels tested.

Dr. Peter J. Snyder of the University of Pennsylvania School of Medicine, who is leading a \$50 million series of trials looking at testosterone treatment in men 65 and older with documented low levels, cautioned against drawing conclusions based on the new study.

"We don't know if these findings apply to men who have low testosterone and meet the criteria for a prescription, or if it applies only to men who have normal levels and then take testosterone in addition," he said.

Dr. Snyder said he and his colleagues found it plausible that testosterone might actually protect against heart disease, in part by reducing body fat and improving blood sugar metabolism.

But, he added, the sharp rise in such prescriptions in the last decade was evidence that many men without testosterone deficiencies were receiving them. "In those cases, there is no medical reason for it," he said, "and that runs counter to all guidelines for physicians." (Source: *The New York Times*, January 29, 2014)

Active Surveillance for Low-Risk Prostate Cancer. Active surveillance for low risk prostate cancer in Canada could save nearly \$100 million annually without worsening quality-adjusted life expectancy (QALE), according to results of a simulation comparing active surveillance with immediate treatment.

Many prostate cancers, especially those in the low-risk category, are indolent and may not require immediate treatment. At least one study has showed that QALE is greater for active surveillance than for brachytherapy, intensity-modulated radiotherapy, or radical prostatectomy.

Still, despite published guideline recommendations, as many as 90% of men with prostate cancer receive immediate treatment. Such overtreatment can be a tremendous financial burden to healthcare systems.

To see how costly it might be, Dragomir, et al., McGill University, Montreal, developed a Markov model with Monte Carlo microsimulations to estimate the direct cost associated with active surveillance and immediate treatment for low-risk prostate in Canada.

They estimated the initial cost of active surveillance at \$1,224, which was considerably lower than the initial cost of radical prostatectomy (\$7,428), brachytherapy (\$8,455), or intensity-modulated radiotherapy plus androgen deprivation therapy (\$14,444).

Even when they accounted for five years of follow-up, the cost of active surveillance rose to only \$1,767, while five years of androgen deprivation therapy amounted to \$23,202.

When the likelihood and cost of delayed treatment was added to the active surveillance strategy, the total cost over five years of follow-up remained considerably lower for active surveillance plus delayed treatment (\$6,200) than for immediate treatment (\$13,735). The absolute cost benefits of active surveillance were maintained during 10 years of follow-up.

Based on an estimated annual cohort of 12,750 patients, the overall cost savings attributable to active surveillance over the first year and five years of follow-up would amount to \$96.1 million. This includes a total savings of \$104.4 million obtained by avoiding treatment in 17.5% of patients who never required treatment and who died from causes other than prostate cancer, and 57.2% of patients still receiving active surveillance, and a supplementary cost of \$8.2

million for delaying treatment for 25.5% of patients.

When the model integrated assumptions from a US study by Keegan et al., the mean cost savings attributable to active surveillance was \$6,416, corresponding to a relative reduction of 52.3% from the cost of immediate treatment.

"With health care costs growing rapidly and access to innovative medicines being limited or restricted by public funding, it is desirable to find ways to increase efficiency," the researchers say. "Furthermore, optimizing the management of low-risk prostate cancer could result in cost reallocation and maximization of health care services offered to patients with prostate cancer."

"The results of our study add to the economic rationale advocating active surveillance for eligible men with low-risk prostate cancer and highlights estimated cost savings specific to the Canadian health system," the authors conclude. (Source: Reuters Health, May 8, 2014, via Medscape Urology)

Additional Resource. Dr. James David, our May 29, 2014, guest speaker, has a website with a large library of mental health articles that may be useful to you, a family member or friend. You can visit it at www.askdrdavidnow.com.

Molecular Test Prompts Changes in Prostate Cancer Treatment Plans. The PROCEED 500 study demonstrated that 65% of physicians changed their original treatment plans for men with prostate cancer based on results from the Prolaris test. Prolaris is a 46-gene molecular diagnostic test that has been evaluated in 11 clinical studies in more than 5,000 patients.

"Prolaris is an absolute game changer for urologists because it adds meaningful new prognostic information in terms of risk assessment for prostate cancer patients that

will improve their care," said E. David Crawford, MD, head of the Section of Urologic Oncology at the University of Colorado in Aurora. "In this study, Prolaris led to major changes in therapies with significant reductions or increases in interventional treatments that were based on patients' unique risk profiles."

PROCEDE 500 is a prospective registry study that was designed to evaluate the impact of the Prolaris test on physician treatment recommendations for patients with prostate cancer. In this study of 305 patients, physicians said they would change their treatment plans in 65% of cases after receiving the Prolaris report. These changes resulted in 40% of patients having a reduced therapeutic burden, while 25% had an increased therapeutic burden— independent of treatment strategy (i.e., surgery and/or radiation vs active surveillance and/or watchful waiting).

The study also found there was an overall 50% reduction in surgical interventions and a 30% reduction in radiation treatment. In addition, 96% of the 24 patients with initial undecided treatment regimens selected noninterventional options after receiving the Prolaris score. These results demonstrate that the Prolaris test is associated with high clinical utility among urologists.

"In multiple clinical studies, Prolaris was shown to provide personalized risk of cancer-specific death, metastases, or biochemical failure beyond what is achievable with the Gleason score, clinical stage, and PSA data," said Michael Brawer, MD, vice president of Medical Affairs at Myriad Genetic Laboratories, Salt Lake City, Utah. (Note: Myriad is the producer of Prolaris)

"More than 30,000 men will die from prostate cancer this year, so there is an urgent need to improve clinical care for patients," said Brawer. "Prolaris adds real value to the health care system by reducing unnecessary surgeries or exposure to radiation for

men at low risk, while increasing medical interventions for men with aggressive prostate cancer, which we believe will save and improve more lives and potentially save the health care system more money." The study was reported in *Current Medical Research and Opinion* (2014).

Interim data from PROCEDE 500, a clinical utility study of the test, were presented at the Genitourinary Cancers Symposium in San Francisco. (Source: OncologyNurseAdvisor, March 31, 2014)

Drug Shows Promise in Advanced Prostate Cancer When Used Before Chemotherapy. The prostate cancer drug Xtandi prolonged lives and delayed tumor progression when used before chemotherapy in a study of men with advanced cases of the disease, researchers said.

The study results are expected to open up a broader market for Xtandi, which was developed by Medivation and Astellas Pharma, and open a new front in its competition with Johnson & Johnson's blockbuster drug Zytiga.

Xtandi, also known as enzalutamide, was approved in 2012 as a treatment for men with metastatic prostate cancer who have already tried the chemotherapy drug docetaxel. The new study showed it was also effective when used before chemotherapy.

Doctors said that could be a welcome option for the tens of thousands of men each year who have advanced prostate cancer but little or no pain or other symptoms. Many of them would rather take a pill like Xtandi or Zytiga than go for periodic infusions of chemotherapy, with its harsh side effects. Zytiga is approved for use both before and after chemotherapy.

The study, which was sponsored by Medivation and Astellas, involved 1,717 men in various countries with cancer that had spread beyond the prostate and was no longer responding to therapy aimed at suppressing testosterone, which fuels cancer growth.

The estimated median survival for the men who received Xtandi was 32.4 months after taking the drug compared with 30.2 months for those who received a placebo, a difference that was statistically significant.

Xtandi also reduced the risk of the cancer worsening by 81 percent, using a measure known as the hazard ratio. The men who took Xtandi were able to delay the median time before they needed chemotherapy by 17 months compared with those who got the placebo.

The trial started in September 2010 and had been expected to last until this September. But the drug was so effective that the trial was stopped early, in October, and the basic results were announced then. But Wall Street analysts were awaiting the full details for clues as to how Xtandi might do against Zytiga.

Dr. Tomasz M. Beer, a principal investigator in the study, said it was not valid to compare the two because they were not tested in a trial directly against each other. Dr. Beer, of the Oregon Health & Science University, was scheduled to present the results this week at the Genitourinary Cancers Symposium in San Francisco.

Still, Geoffrey Meacham, an analyst at JPMorgan who follows Medivation, said

in a note Tuesday that the results were “very impressive and helped solidify Xtandi’s place ahead of Zytiga in the pre-chemo setting.”

The full results could allay concerns about the most worrisome side effect of Xtandi: seizures. There were only two seizures, and one was in the placebo group.

“I think that is very reassuring,” Dr. Beer said in a telephone news conference, noting that efforts were made to exclude patients with a known risk of seizures from the study. (Source: The New York Times (Health), January 25, 2014)

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"HORMONE THERAPY 101"
by
MICHELE OJEMUYIWA, MD
DEPARTMENT OF UROLOGY
WALTER REED NATIONAL MILITARY MEDICAL CENTER

(Summary of a presentation to the WRNMMC Prostate Cancer Support Group, February 6, 2014)

(Editor's Note: Dr. Ojemuyiwa discussed basic issues affecting the patient's decision to undergo hormone therapy in dealing with prostate cancer. Audio-visual problems do not allow us to present a verbatim transcript, so this summary relies on the slides Dr. Ojemuyiwa used in her presentation.

Introduction. Dr. Ojemuyiwa reviewed the primary therapies for dealing with prostate cancer (e.g., surgery, radiation), noting that the treatment decision depended on whether the disease was localized or metastatic. Watchful waiting/active surveillance is now receiving greater consideration, especially for older men with lower Gleason scores. She reviewed the Gleason grading system as well as the staging process (localized, locally advanced, and metastatic). Biochemical recurrence occurs in 20-40% of patients after initial primary therapy. It may be locally occult or metastatic. The latter condition is often asymptomatic at diagnosis. Treatment options after recurrence may include additional local therapy, hormonal therapy or watchful waiting. It is virtually impossible to predict the impact of any therapy on survival.

Hormone Therapy Treatment. Hormone therapy is synonymous with androgen deprivation therapy. Charles Huggins showed in 1941 that prostate cancer was inhibited by decreasing testosterone (by castration or estrogen) and stimulated by adding testosterone. Androgen deprivation therapy relies on these testosterone-lowering therapies: hormone manipulation, periodic injection of testosterone-lowering treatment, and orchiectomy (castration). The latter is the more cost-effective approach. Hormonal therapy is indicated for metastatic prostate cancer and recurrence after primary local therapy. Men with high risk localized disease may receive hormonal therapy before, during, and after primary radiation therapy.

Lupron in different formulations is a primary hormonal therapy. The side effects of hormonal therapy can be significant. They include: loss of sex drive, hot flashes, breast development, muscle loss, weight gain, fatigue, cardiovascular risk, and diabetes. So why use hormones? Androgen deprivation therapy induces remission of prostate cancer in 80-90% of men with advanced disease. It results in a median progression-free survival of 18-24 months.

Over time, traditional hormonal therapies become less effective. Tumors develop mechanisms of resistance, such as developing increased sensitivity to low levels of testosterone, and they even produce their own forms of testosterone.

Hormone Therapy and Sexual Dysfunction. Sexual dysfunction usually occurs within the first several months of hormonal therapy, evidenced initially by loss of libido, then by erectile dysfunction. These conditions can be reversed by discontinuance of androgen deprivation therapy, anti-androgen monotherapy, or intermittent androgen deprivation therapy.

Dr. Ojemuyiwa then presented slides discussing the several developments in anti-androgen therapy, chemotherapy, and therapeutic cancer vaccines, e.g., Sipuleucel-T (Provenge), Abiraterone, Cabazitaxel, and Docetaxel, citing the clinical trials involving them. She then described some of the cutting-edge clinical trials underway at the National Institutes of Health and encouraged the audience to consider participating in them.

◆ **WRAMC US TOO COUNSELORS** ◆

(As of May 1, 2014)

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

SURGERY

Tom Assenmacher	Kinsvale, VA	(804) 472-3853	
Jack Beaver	Falls Church, VA	(703) 533-0274	1998 (Open RP)
Gil Cohen	Baltimore, MD	(410) 367-9141	
Richard Dorwaldt	San Antonio, TX	(210) 310-3250	(Robotic Surgery)
Michael Gelb	Hyattsville, MD	(240) 475-2825	(Robotic Surgery)
Robert Gerard	Carlisle, PA	(717) 243-3331	
Tony Giancola	Washington, DC	(202) 723-1859	2013 (Radical Prostatectomy)
Ray Glass	Rockville, MD	(301) 460-4208	
Monroe Hatch	Clifton, VA	(703) 323-1038	
Tom Hansen	Bellevue, WA	(425) 883-4808	1998 (Robotic Surgery)
Bill Johnston	Berryville, VA	(540) 955-4169	
Dennis Kern	San Francisco, CA	(415) 876-0524	
Sergio Nino	Dale City, VA	(703) 590-7452	
Ed Postell	Collegetown, PA	(610) 420-6765	(Robotic Surgery)
George Savitske	Hellertown, PA	(703) 304-3081	2000 (Open RP)
Artie Shelton, MD	Olney, MD	(301) 523-4312	
Jay Tisserand	Carlisle, PA	(717) 243-3950	
Don Williford	Laurel, MD	(301) 317-6212	2000 (Open RP)

PROSTATE CANCER AND SEXUAL FUNCTION

James Padgett	Silver Spring, MD	(301) 622-0869
George Savitske	Hellertown, PA	(703) 304-3081

RADIATION

Leroy Beimel	Glen Burnie, MD	(410) 761-4476	1987 (External Beam Radiation)
Bob Bubel	Grand Junction, CO	(970) 263-4974	2010 (Proton Beam Radiation)
Harvey Kramer	Silver Spring, MD	(301) 585-8080	1998 ((Brachytherapy)
Bill Melton	Rockville, MD	(301) 460-4677	2001 ((External Beam Radiation)
Joseph Rosenberg	Kensington, MD	(301) 495-9821	2009 (Brachytherapy)
Barry Walrath	McLean, VA	(571) 969-8269	2001 (Brachytherapy)

INCONTINENCE

Ray Walsh	Annandale, VA	(703) 425-1474
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WATCHFUL WAITING

Tom Baxter	Haymarket, VA	(703) 753-8583	Active Surveillance
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SPOUSE SUPPORT

Renate Bubel	Fairfax, VA	(703) 280-5765
Karen Collins	Mechanicsburg, PA	(717-766-6464
Betty Kramer	Silver Spring, MD	(301) 585-8080
Ellen Rosenberg	Kensington, MD	(301) 495-9821
Nancy Wallrath	McLean, VA	(703) 915-8108

OTHER THERAPIES/MULTIPLE THERAPIES

Howard Bubel	Fairfax, VA	(703) 280-5765	1995,1996 (Hormonal, Cryosurgery, Sexual Function)
Arthur E. Clough	Kerryville, TX	(830) 896-8826	1993 (Surgery and Radiation)
Pete Collins	Mechanicsburg, PA	(717) 766-6464	2007, 2009 (Surgery, Radiation, Hormonal)
Charles Preble	Annandale, VA	(703) 560-8852	(Cryosurgery, Hormonal)
Ray Walsh	Annandale, VA	(703) 425-1474	1999, 2001 ((Surgery and Hormonal)

◆ MEETING ANNOUNCEMENT ◆

THURSDAY, MAY 29, 2014
7 - 8:30 PM

AMERICA BUILDING (2D FLOOR)
ROOM 2525
(DIRECTLY ABOVE THE LAB/PHARMACY)
WALTER REED NATIONAL MILITARY MEDICAL CENTER

◆ SPEAKERS ◆

JAMES DAVID, PhD
(PRIVATE PRACTICE)
and
PETER FAGAN, MD
ASSOCIATE PROFESSOR, THE JOHNS HOPKINS UNIVERSITY
SCHOOL OF MEDICINE

TOPIC

"LIFE WITH CANCER: PRACTICAL TOOLS FOR LIVING WITH
UNCERTAINTY"

Gate/Parking: If you enter the base through South Gate (Gate 2) off Rockville Pike/Wisconsin Ave, take the first right (Palmer Road South). On your left you will see the Emergency Room. Continue to follow signs to the America Building and the America parking garage.

Security: A military ID is required to get on base. Persons without a military-related ID card who are attending the meeting are required to register in advance in order to gain entry. To register, contact the CPDR front desk at 301-319-2900 no later than two business days prior to Thursday, May 29, 2014 to arrange for entry. Have a photo ID card ready when arriving at the gate

