Us TOO® PROSTATE CANCER EDUCATION & SUPPORT

HOTSHEET

December 2009

WHY I DONATE TO US TOO INTERNATIONAL

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

Bottom Line: Imagine if Us TOO took a break or did not exist! Millions of men and their loved ones would not receive their life saving information and support. This has been a tough year for all cancer organizations, Us TOO is no exception, so this is the year that Us TOO needs you the most of all. COME ON! SEND THEM A FINANCIAL HOLIDAY GIFT THAT CAN SUPPORT THEM IN 2010.

Us TOO has been there from the beginning helping men with prostate cancer educate themselves so that they could make the right decisions for themselves. Us TOO has also made the job of almost all prostate cancer health care professionals easier by providing this unlimited support. Us TOO fights for you, and battles to get the latest in novel drug treatments to the public as fast as humanly possible. Us TOO was there in Washington DC when we privately met with the head of the FDA to understand how the PROVENGE® vaccine could move forward. Us TOO fights on the state, national and worldwide scene to in-

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AUA RELEASES STATEMENT CLARIFYING PROSTATE CANCER TESTING RECOMMENDATIONS

The American Urological Association (AUA) today released a statement on prostate cancer testing, clarifying the Association's recommendations and support of early detection.

The American Urological Association (AUA) is aware of recent news reports disparaging prostate cancer testing. We are concerned that these reports are causing significant confusion for patients and we wish to clarify our recommendations on prostate cancer testing with the prostate-specific antigen (PSA) test and digital rectal exam (DRE). The AUA strongly supports early prostate cancer detection and feels it is in a man's best interest to consider being tested for prostate cancer.

Prostate cancer is most treatable when caught early. Men ages 40 and older should be offered a baseline PSA test and DRE for early detection and risk assessment. The future risk of prostate cancer is closely related to a man's PSA score; men who are screened at 40 establish a baseline PSA score that can be tracked over time. The AUA strongly supports informed consent,

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DENDREON COMPLETES SUBMISSION OF BIOLOGICS LICENSE APPLICATION FOR PROVENGE®

Dendreon Corporation announced that it has completed the submission of the amended Biologics License Application (BLA) for PROVENGE (sipuleucel-T), the Company's lead investigational product, to the FDA. Dendreon is seeking licensure for PROVENGE metastatic castrate-resistant prostate cancer (CRPC). If approved by FDA, PROVENGE would represent the first product in the new therapeutic class known as active cellular immunotherapies.

The amended BLA includes data from the IMPACT (IMmunotherapy for Prostate AdenoCarcinoma Treatment) trial, which was conducted under a Special Protocol Assessment agreement with the FDA. The IMPACT study met its pre-specified primary endpoint demonstrating a statistically significant improvement in overall survival in men with metastatic CRPC.

"With the BLA submission complete, we have taken an important step towards reaching our goal of bringing a new therapy to men with advanced prostate cancer," said Mitchell H. Gold, MD, president and chief executive officer of Dendreon. "We look

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ANALYSIS QUESTIONS BREAST AND PROSTATE CANCER SCREENING

Two decades after the explosion in cancer screening fueled by reimbursement for mammography and prostate specific antigen (PSA) testing, a new analysis suggests that it is time to rethink the push for early detection of these two cancers.

There is no argument that more cancers are being detected and at a much earlier stage, but that increase has not resulted in a decrease in metastatic disease, according to Laura Esserman, MD, MBA, of the University of California, San Francisco, and colleagues, who made their case in a special communication published in the 21 October issue of the *Journal of the American Medical Association* (Vol.302, pp. 1685-92, 2009).

In broad strokes they painted a picture of increased detection and costly treatment of cancers that pose minimal risk, without making a dent in killer cancers. The researchers touched a nerve with the commentary, and the American Cancer Society has already gone on record saying that it is reconsidering its position on the risks and benefits of breast and prostate cancer screening.

Otis Brawley, MD, chief medical officer of the society told The New York Times, that the benefits of screening have been exaggerated.

"It is very appropriate that we occasionally step back, assess and reflect on what we in medicine are doing," Brawley added. "In the case of some screening for some cancers, modern medicine has overpromised. Some of our successes are not as significant as first thought. Cancer is a complicated disease and too often we have tried to simplify it and simplify messages about it, to the point that we do harm to those we want to help."

In the JAMA paper, Esserman wrote that the screening push seemed like a logical way to reduce cancer mortality. For both breast and prostate cancer "there are remarkable differences between outcomes of localized versus advanced disease (breast cancer: five-year relative survival rates of 98.1% versus 27.1%; prostate cancer: 100% versus 31.7%)."

And the penetration of the screening has been significant – 70% of women 40 or older say they have had a recent mammogram, and 50% of at-risk men have routine PSA testing.

But when prostate cancer mortality in the US was compared with the rate in UK – where PSA screening is not recommended – there was no difference, although the incidence of prostate cancer was dramatically higher in the US. For breast cancer, seven randomized trials found a relative reduction in mortality ranging from 20% to 30%, but the "observed decrease in mortality is attributable to both screening and adjuvant therapy, with an estimated decrease of 7% to 23%, and 12% to 21%, respectively."

Esserman suggested that the problem may be that early detection "may not be the solution for aggressive cancers because many may not be detected early enough for a cure."

What is an effective screening technique is the detection of premalignant lesions, which is exactly what occurs with both colonoscopy and pap smears, two screening strategies that have significantly decreased invasive colorectal and cervical cancers.

Esserman argued that it is time to develop new screening strategies – possibly new biomarkers – that will be able to differentiate between "significant- and minimal-risk cancers." At the same time, she recommended new strategies to "reduce treatment for minimal-risk disease" and called for the development of "clinical and patient tools to support informed decisions about prevention, screening, biopsy, and treatment, and offer treatments tailored to tumor biology."

The article "grew out of collaboration initiated within the Early Detection Research Network and was supported by grants U01CA111234 and U01CA086402."

UCSF Department of Public Affairs
20 October 2009

MedPage Today, 21 October 2009

AMERICAN CANCER SOCIETY STANDS BY ITS SCREENING GUIDELINES; WOMEN ENCOURAGED TO CONTINUE GETTING MAMMOGRAMS

Statement of Otis W. Brawley, MD, Chief Medical Officer, American Cancer Society in Response to New York Times Article on Cancer Screening

"Today's New York Times article 'In Shift, Cancer Society Has Concerns on Screening' indicates that the American Cancer Society (ACS) is changing its guidance on cancer screening to emphasize the risk of overtreatment from screening for breast, prostate, and other cancers.

"While the advantages of screening for some cancers have been overstated, there are advantages, especially in the case of breast, colon and cervical cancers. Mammography is effective – mammograms work and women should continue get them. Seven clinical trials tell us that screening with mammography and clinical breast exam do reduce risk of breast cancer death. This test is beneficial in that it saves lives, but it is not perfect. It can miss cancers that need treatment, and in some cases finds disease that does not need treatment. Understanding these limitations will help researchers develop better screening tests. ACS stands by its recommendation that women age 40 and over should receive annual mammography, and women at high risk should talk with their doctors about when screening should begin based on their family history.

"The bottom line is that mammography has helped avert deaths from breast cancer, and we can make more progress against the disease if more women age 40 and older get an annual mammogram. Since 1997 the ACS has recommended that men talk to their doctor and make an informed decision about whether or not prostate cancer early detection testing is right for them. This recommendation also still stands."

"Cancer is a very complex and complicated disease. The ACS makes evidence-based cancer screening recommendations, and strives to provide clear messages about cancer screening to patients and doctors. Our guidelines are constantly under review to evaluate them as new evidence becomes available. Simple messages are not always possible, and over-simplifying them can in fact do a disservice to the very people we serve."

ACS combines an unyielding passion with nearly a century of experience to save lives and end suffering from cancer. As a global grassroots force of more than three million volunteers, we fight for every birthday threatened by every cancer in every community. We save lives by helping people stay well by preventing cancer or detecting it early; helping people get well by being there for them during and after a cancer diagnosis; by finding cures through investment in groundbreaking discovery; and by fighting back by rallying lawmakers to pass laws to defeat cancer and by rallying communities worldwide to join the fight. As the nation's largest non-governmental investor in cancer research, contributing about $3.4 billion, we turn what we know about cancer into what we do. As a result, more than 11 million people in America who have had cancer and countless more who have avoided it will be celebrating birthdays this year.

To learn more about us or to get help, call us anytime, day or night, at 1-800-227-2345 or visit <www.cancer.org>.

ACS, 21 October 2009

AUA CLARIFIES PROSTATE CANCER TESTING RECOMMENDATIONS *(Continued from page 1)*

including a discussion about the benefits and risks of testing, before screening is undertaken.

According to the American Cancer Society (ACS), prostate cancer is the most common non-skin cancer affecting men in the US. One in six men will be diagnosed with prostate cancer in his lifetime – more than 192,000 in 2009. It is the second leading cause of cancer death in American men.

Prior to the emergence of PSA testing, only 68 percent of newly diagnosed men had cancer localized to the prostate and 21 percent had metastatic disease. Today, more than 90 percent of these men have cancer confined to the prostate and only 4 percent have cancer that has spread to other areas of the body. US deaths from prostate cancer have decreased by 40 percent over the past decade – a greater decline than for any other cancer. While the PSA test may be limited because it does not indicate whether a cancer is aggressive, the test provides important information in the diagnosis, pretreatment staging or risk assessment, and monitoring of prostate cancer patients. It has allowed millions of men to make informed treatment decisions that may have saved their lives.

The controversy over prostate cancer should not surround the test, but rather how test results influence the decision to treat. The decision to proceed to prostate biopsy should be based not only on elevated PSA and/or abnormal DRE results, but should take into account multiple factors including free and total PSA, patient age, PSA velocity, PSA density, family history, ethnicity, prior biopsy history and comorbidities.

A cancer cannot be treated if it is not detected. Not all prostate cancers require immediate treatment; active surveillance, in lieu of immediate treatment, is an option that should be considered for some men. Testing empowers patients and their urologists with the information to make an informed decision.

The above statement may be attributed to AUA Past President John M. Barry, MD. The AUA Best Practice Statement on Prostate-Specific Antigen can be viewed here: <www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/psa09.pdf>.

Vocus/PRWEB, 2 November 2009

DOC MOYAD

(Continued from page 1)

crease funding for prostate cancer. Us TOO continues to team up with other prostate and non-prostate cancer organizations to do whatever is needed to help prostate cancer patients and their families!

I am one of the last individuals that should be financially contributing to Us TOO because I am a monthly volunteer, but I recognize that as much as I believe that I am doing for this organization, it has done much more for me and the thousands of patients that I have tried to educate and help over my career. This was a terrible year financially for almost all charitable organizations because the economy was so pathetic, but this is exactly why I also believe I can give up just one evening of going out for a meal and drinks to do my part for this incredible organization. I challenge you to do the same!

Can you imagine a world without over 300 prostate cancer support groups, no monthly *HotSheet*, no resources for men with newly diagnosed, already treated and recurring disease, or for men with advanced prostate cancer in desperate need of help?!

I cannot imagine this, just like I cannot imagine going a month without writing my column for Us TOO, except this month I am going to skip my monthly column just to implore you to do the right thing for this holiday season, and give just a little to an organization that is one of our only voices in an area of medicine ridiculously under-funded and under-appreciated.

FDA SAYS NO TO AN AMGEN BONE DRUG

Amgen has failed to win approval from the FDA, for now at least, for the bone-strengthening drug, denosumab, that the company has been counting on to propel its growth. The company said that the FDA had instead asked for more information – though not new clinical trials – for the drug, denosumab. The drug is meant to be a treatment for osteoporosis, the bone-thinning disease, in women who have passed through menopause. In August, an advisory committee to the FDA had voted 15-0 in August in favor of approval of denosumab to treat osteoporosis, but 12-3 against approval for preventing it.

Recently, some Wall Street analysts had speculated that the FDA would delay its decision on denosumab by 90 days past Monday's deadline. Such a delay is not uncommon because the agency's staff is stretched thin. But the FDA instead issued a "complete response" letter, essentially a rejection, which could possibly delay approval well beyond 90 days.

Analysts have predicted that denosumab, which Amgen would sell under the name Prolia, could reach sales of at least $1 billion a year, and possibly much more. Amgen needs a hit product because sales of Aranesp, its flagship drug for anemia, have been hurt by safety concerns. And growth in sales of its other big-selling drugs has slowed.

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SAVE THE DATES!

August 20-21, 2010

Us TOO
20th Anniversary
Celebration &
Symposium

Chicago, IL

Watch for more info at
www.ustoo.org

PROVENGE

(Continued from page 1)

forward to working with the FDA to potentially make PROVENGE the first active cellular immunotherapy to be licensed in the United States."

PROVENGE is available through several ongoing clinical trials, including OpenACT, an open label trial enrolling men with metastatic CRPC, Pro-ACT (PROstate cancer Active Cellular immunoTherapy), and NeoACT (NEOadjuvant Active Cellular immunotherapy). For more information regarding these studies, visit <www.clinicaltrials.gov>.

About PROVENGE

PROVENGE is Dendreon's investigational product candidate for men with advanced prostate cancer and may represent the first in a new class of active cellular immunotherapies (ACIs) specifically designed to engage the patient's own immune system against cancer. PROVENGE and other ACIs are uniquely designed to use live human cells to engage the patient's own immune system with the goal of eliciting a specific long-lasting response against cancer.

This news release contains forward-looking statements that are subject to risks and uncertainties. Factors that could affect these forward-looking statements include, but are not limited to, developments affecting Dendreon's business and prospects, including the FDA's actions with respect to the BLA and whether the FDA determines to convene an advisory committee to review the BLA; progress on the commercialization efforts for PROVENGE, including the expansion of Dendreon's manufacturing capacity and other necessary infrastructure; success in the hiring of additional personnel to support business growth and expansion; the outcome of pre-approval inspection of Dendreon's expanded manufacturing facility; and requisite receipt of FDA licensure for marketing of PROVENGE and the risk that additional capital could be needed in the future for the potential commercialization of PROVENGE. Information on the factors and risks that could affect Dendreon's business, financial condition and results of operations are contained in Dendreon's public disclosure filings with the U.S. Securities and Exchange Commission, which are available at <www.sec.gov>. Dendreon cautions investors not to place undue reliance on the forward-looking statements contained in this press release. All forward-looking statements are based on information currently available to Dendreon on the date hereof, and Dendreon undertakes no obligation to revise or update these forward-looking statements to reflect events or circumstances after the date of this press release, except as required by law.

Dendreon Corporation, 2 November 2009

RADICAL PROSTATECTOMY FINDINGS IN PATIENTS IN WHOM ACTIVE SURVEILLANCE OF PROSTATE CANCER FAILS

Duffield AS, Lee TK Miyamoto H, Carter HB, Epstein JI

J Urol 182(5): 2274-8, 2009

Little data are available on radical prostatectomy findings in men who experience disease progression following active surveillance.

A total of 470 men in our active surveillance program underwent annual repeat needle biopsies to look for progression defined as any Gleason pattern grade 4/5, more than 50% cancer on any core or cancer in more than 2 cores. Slides were available for review in 48 of 51 radical prostatectomies with progression.

The average time between the first prostate biopsy and radical prostatectomy was 29.5 months (range 13 to 70), with 44% and 75% of the patients showing progression by the second and third biopsy, respectively. There were 31 (65%) organ confined cases, of which 25 (52%) were Gleason score 6. Of 48 cases 17 (35%) had extraprostatic extension, 3 had seminal vesicle/lymph node involvement and 7 (15%) had positive margins. Mean total tumor volume was 1.3 cm^3 (range 0.02 to 10.8). Of the 48 tumors 13 (27%) were potentially clinically insignificant (organ confined, dominant nodule less than 0.5 cm^3, no Gleason pattern 4/5) and 19% (5 of 26) of the radical prostatectomies with a dominant tumor nodule less than 0.5 cm^3 demonstrated extraprostatic extension, 4 with Gleason pattern 4. All 10 tumors with a dominant nodule greater than 1 cm^3 were located predominantly anteriorly.

Most progression after active surveillance occurs 1 to 2 years after diagnosis suggesting undersampling of more aggressive tumor rather than progression of indolent tumor. Even with progression most tumors have favorable pathology (27% potentially insignificant). A small percentage of men have advanced stage disease (pT3b or N1). The anterior region should be sampled in men on active surveillance.

CLINICIANS MAP GROUP AT HIGH RISK FOR AGGRESSIVE, "HIDDEN" PROSTATE CANCER

Clinical researchers at Princess Margaret Hospital (PMH) can now answer the question that baffles many clinicians why do some men with elevated prostate specific antigen (PSA) levels who are carefully monitored and undergo repeated negative biopsies still develop aggressive prostate cancer?

The answer is hidden tumors located on the top of the prostate that evade traditional diagnostic procedures, including ultrasound-guided needle biopsy. The PMH research, published online in the British Journal of Urology International demonstrates that magnetic resonance imaging (MRI) is the best tool to reveal such tumors.

"Our findings identify a specific high-risk group whose tumors are difficult to diagnose because of location. These men benefit from MRI, which guides the biopsy procedure with a high degree of accuracy," says author Dr. Nathan Lawrentschuk, Urologic Oncology Fellow, PMH Cancer Program, University Health Network. "The research team calls the presentation of elevated PSA and repeated negative biopsy results in 'prostate evasive anterior tumor syndrome' (PEATS)."

"Knowing about PEATS may also be important for men already on 'active surveillance' - patients with slow - growing prostate cancer who are being regularly monitored through PSA testing and biopsy. Every man does not need an MRI, but knowing about PEATS will help us identify those who do," says principal investigator Dr. Neil Fleshner, Head of the Division of Urology, Princess Margaret Hospital, and Professor of Surgery at University of Toronto.

A team of urologists, surgeons, radiologists and pathologists studied 31 PMH patients who had positive biopsy results and tumors on top of their prostate as shown on MRI. They found that MRI was able to help diagnose hidden prostate tumors 87% of the time.

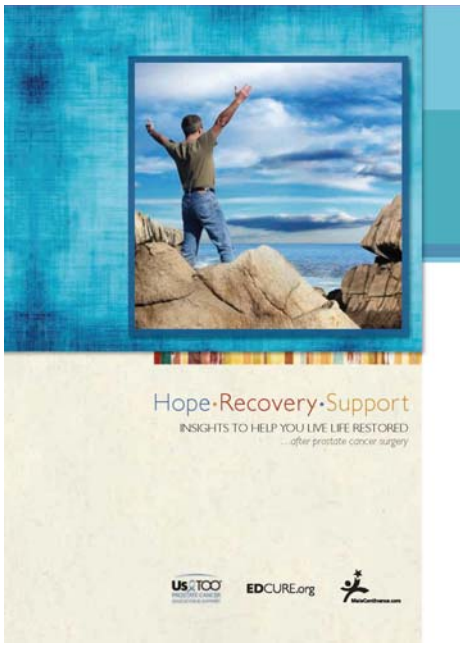
Dr. Lawrentschuk says clinicians need to be aware of PEATS because these hidden tumors can be aggressive.

Medical News Today, 09 October 2009

NEW POST-SURGERY GUIDE TO RESTORATION OF SEXUAL HEALTH AND CONTINENCE NOW AVAILABLE

Us TOO is pleased to announce the release of a valuable new resource, ***The Prostate Cancer Recovery Guide: Hope, Recovery, Support – Insights to help you live life restored after prostate cancer surgery.***

This 71-page booklet is designed to provide you with important information about what to expect after your prostatectomy, helping you track your progress, providing support options and other important things to know in the months following your surgery.



The guide is organized into seven sections covering What to expect post-surgery, Regaining continence, Restoring your sexual health, Tracking your progress, Frequently asked questions, Resources and a Glossary.

Copies of the guide were shipped to Us TOO support group chapters last month to distribute to their local members.

You can also read the entire publication online or request a your own copy by using the Us TOO Online Information Request Center at <www.ustoo.org/freematerials>.

Special thanks go to EDCure.org and MaleContinence.org who produced and shared the guide with Us TOO, and to the Us TOO volunteer reviewers.

ASK DR. SNUFFY MYERS

You've got questions about prostate cancer. Dr. Myers has answers. That's all you need to know. To submit your question, please email it to ustoo@ustoo.org.

Dear Dr. Myers,

"My pharmacist tells me that 150 mg per day of Casodex® is not FDA approved. (50 mg is approved.) In your book you recommend 150 mg of Casodex for high-risk patients. Can one obtain 150 mg of Casodex?"

There appears to be a great deal of misunderstanding about the impact of FDA approval on physician use of drugs. In fact, if a drug is approved by the FDA and on the market, it can be used for other conditions. This is allowed because of a limitation in our system of drug development and approval. It costs several million dollars to get a drug approved for a disease or condition. There are many situations where the market size is not lucrative enough to attract the interest of the pharmaceutical companies. Market size is not the only limiting factor.

For prostate cancer, the major acceptable end point for a clinical trial is survival. For many presentations of prostate cancer, patients do not start to die until 10 to 20 years after diagnosis. The life of the patent on the drug is likely to run out before a pharmaceutical firm can recoup their costs and generate enough profit to make the investment attractive. The paragraph below is from the FDA guidance on the off-label use of drugs, which was updated in March 2009. Without the option of using off-label drugs, there would be very few treatment options for many men with prostate cancer.

"Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects."

As you point out, Casodex is FDA approved in a 50 mg size, but not in a 150 mg size. The solution is simply to take three of these 50 mg pills. I should point out that Casodex is now available as the generic, bicalutamide.

Casodex is a pure antiandrogen. There are two other pure antiandrogens – Eulexin® (flutamide) and Nilandron® (nilutamide). All three drugs have the capacity to cause liver damage with Eulexin being the worst offender. After two literature reports indicated that Actigall® (ursodiol) was able to reverse liver damage due to Eulexin, we have then gone on to show that this drug can reverse liver toxicity due to Casodex. I recommend patients take Actigall in a prophylactic fashion to prevent any risk of liver damage. The dose is 300 mg two or three times per day.

About Dr Myers:

Medical oncologist and prostate cancer survivor, Dr. Charles "Snuffy" Myers was a key player in creating AZT, suramin, and phenylacetate while working at the National Institute of Health. With over 250 research papers published, Myers is one of the leading developers of today's prostate cancer canon on both the research and treatment side of the test tube. Prostate Forum is the educational arm of his world-renowned practice that is dedicated to providing men with the comprehensive care that saved his own life.

US TOO INTERNATIONAL PARTICIPATES IN COMBINED FEDERAL CAMPAIGN

Military and federal employees – Please remember Us TOO International in the 2009 Combined Federal Campaign! **Use CFC# 11614.**

Thank you!

RANDOMIZED TRIAL OF EXTERNAL BEAM RADIOTHERAPY VS. CRYOABLATION IN PATIENTS WITH LOCALIZED PROSTATE CANCER: QUALITY OF LIFE OUTCOMES

In the 18 August 2009 online edition of the journal *Cancer*, Dr. John Robinson and associates present Quality of Life (QoL) outcomes from a single institution randomized trial comparing external beam radiotherapy (EBRT) with cryotherapy (CT) for localized prostate cancer. They previously reported a non-inferiority oncologic outcome for cryotherapy in this study.

The trial ran from 1997 to 2003, and 122 prostate cancer patients were randomized to EBRT and 122 to CT. Neoadjuvant hormone therapy was given for 3 months in 160 patients and 6 months in 71 patients. QoL was assessed by the EORTC QLO C30 and the UCLA Prostate Cancer Index prior to treatment and at 1.5, 3, 6, 13, 24, and 36 months after treatment. Domains assessed in the EORTC QLO C30 include physical activity, emotional state, social interaction, global health, and symptom scales. The UCLA Prostate Cancer Index assesses sexual, urinary, and bowel functions.

EORTC QLO C30 domains demonstrated an increase in symptoms after either treatment with the exception of insomnia and more EBRT patients experienced insomnia at 3 and 24 months compared with CT patients. The average urinary bowel and sexual function scores demonstrated differences. CT patients reported lower urinary function scores (69.4 vs. 90.7), similar bowel function, and lower sexual function scores (7.2 vs. 32.9). At 36 months EBRT men had slightly lower urinary function scores but no difference in bowel function scores. The CT patients had lower sexual function scores at 36 months (16 vs. 36.7). The proportion of CT patients with urinary bother increased from 1% at baseline to 29.3% at 6 weeks with no long-term effects at 36 months.

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THE DOCTORS NOTE – GERALD CHODAK, MD

Here we go again; yet more about screening, a topic that that does not disappear.

First let me clarify my position which is so often misrepresented. I am not now nor have I ever been against screening. However, I am against giving messages to the public that are not supported by sound scientific studies. Until recently, the message to the public has been that screening should be done because it will save so many lives, but no data supported that position. Now, we finally have some good, though not perfect information from recent studies that begins to address that message and we find that the message really has been greatly exaggerated; yes there is some benefit but it is extremely small and it causes a major problem of over treatment.

The article by Esserman and colleagues (*JAMA*) also challenges the message by comparing the US, where about 70% of men are getting screened against the UK, where limited screening has occurred. Their finding: little to no difference in prostate cancer mortality rates. In reaction to this publication, the American Cancer Society issued a recent statement that also stated that the benefit of PSA screening has been exaggerated to the public.

At the same time, the AUA has clarified its recent recommendation that all men should get a baseline PSA starting at age 40 because '*if you don't find it early you can't treat it early*.'

There are no prospective studies that demonstrate conclusively that following this recommendation will reduce mortality or improve upon the recent PLCO and ERSPC findings and there are no data about how many men will have to be treated to prevent one cancer death. None of these deficiencies is acknowledged in the new statement.

There is no doubt that baseline PSA testing at an earlier age will reassure some men that their risk of ever getting cancer is low, but what is the tradeoff? Will it result in even more men getting unnecessary therapy and a compromised quality of life?

Although having a diagnosis of cancer does not have to result in treatment, how many men in their 40's who are found to have cancer will be willing to forego immediate therapy? Undoubtedly it will be very few. They are likely to view the study cited in this issue by Duffield and colleagues of radical prostatectomy findings in men who had been on active surveillance. Of the 470 men in their program, 48 needed treatment of which 17 (3.6%) had cancer outside the prostate on their radical prostatectomy specimen.

Even those small numbers of potentially incurable cancers will be enough to scare most men into proceeding to immediate treatment. Consequently, shouldn't the public have been told by the AUA that their new recommendation is not supported by a proper study and its impact on the death rate is unknown? Finding early cancers is necessary but definitely not sufficient to justify this policy.

Screening for lung cancer, ovarian cancer and neuroblastoma also finds more early stage cancers, but cancer deaths were not lowered significantly to justify their use. Certainly, people will argue that some of those people still would have benefited. The problem with PSA testing in 50+ year old men is that a portion already have advanced disease by the time the test is abnormal so it would seem logical that they need to be tested even earlier. Unfortunately, PSA testing at 40 still might not be good enough to prevent many of those men from eventually dying because the test may be unable find aggressive tumors before one cancer cell has spread.

What does all this mean for your friends and relatives who do not have the disease? Should they get tested or not? The answer is they should understand the tradeoff and uncertainty and make a choice, but not make that choice based on misinformation. Understanding what is known but also what is not known will help them make a decision.

HORMONE THERAPY CAN HELP SOME WITH PROSTATE CANCER

A brief course of hormone-blocking therapy (HT) can provide small benefits to a specific group of men who get radiation therapy (RT) for prostate cancer, a long-running study shows.

Ten-year survival was 62 percent in men with cancers graded as intermediate risk who got HT in addition to RT, compared to 57 percent of those who got RT alone, said Dr. Christopher U. Jones, a radiation oncologist at Radiological Associates of Sacramento, a member of the group reporting the results at the 2009 American Society for Therapeutic Radiation Oncology meeting. Biopsies taken from men showed no traces of cancer in 78 percent of those having combined HT+RT vs. 60 percent in those getting RT alone.

The benefit is statistically significant but not huge, because "we weren't expecting large differences" in such cases, Jones said. And while study results already are incorporated in medical practice, it is not the final word on the issue, since "the standard of care in RT has changed since the study began in 1994," Jones said. "We can now localize treatment more so we give higher doses of RT, 50 percent higher."

Even the definition of "intermediate risk" has evolved, he said. It is now based on such factors as levels of PSA and Gleason score. "Since the study opened, we have more data and are better able to determine who is truly at low risk," Jones said. "Of the 2,000 we enrolled, we now know that 685 were truly low-risk, 1,068 were at intermediate risk and 226 were high-risk."

"For the low-risk group, there is very little benefit in adding HT, Jones concluded. The most benefit is for those at intermediate risk, with high-risk patients in the middle." In other words, "what we can show in this study is that patients can be spared HT if they fit the modern definition of low-risk." That can be a big help, since side effects of HT include impotence and hot flashes.

He also suggested that modern RT might eliminate the need for HT in intermediate risk patients.

HealthDay News, 2 November 2009

FDA SAYS NO TO DENOSUMAB *(Continued from page 4)*

In a news release Monday morning, Amgen said the FDA had asked for several items before it could approve denosumab to treat osteoporosis, including more information on the studies the company would perform after the drug is approved. The agency is also still discussing Amgen's plans for limiting the risks from the drug's use.

Analysts have generally stated that they expect Amgen to be able to satisfy the FDA's requirements.

"We are confident that we can quickly respond to the FDA's request for the treatment of postmenopausal osteoporosis indication and plan to do so in the near term," Dr. Roger M. Perlmutter, the company's executive vice president for research and development, said in a statement.

Amgen is also expecting a decision soon on its application to sell denosumab as a treatment for the bone loss caused by hormone suppression therapies used to treat breast and prostate cancer. The advisory committee was not very enthusiastic about those uses of the drug.

The main drugs now used to treat the condition are bisphosphonates – including Fosamax, Actonel and Boniva – which are taken as pills every day, or every week or every month. But those drugs can be hard to tolerate, and many patients stop taking them.

Denosumab, which works through a mechanism discovered in Amgen's own laboratories, is a protein called a monoclonal antibody. It would be given by an injection every six months, which could make it easier for patients to remain on therapy.

But insurers are likely to require that patients try bisphosphonates first, particularly since generic Fosamax is now available and likely to be far less expensive than denosumab.

Analysts have predicted that denosumab, which Amgen would sell under the name Prolia, could reach sales of at least $1 billion a year, and possibly much more.

Amgen needs a hit product because sales of Aranesp, its flagship drug for anemia, have been hurt by safety concerns. And growth in sales of its other big-selling drugs has slowed.

New York Times, 20 October 2009

EBRT VS CT

(Continued from page 6)

Bowel bother for EBRT patients increased from 2.6% at baseline to 10.3% at 36 months and moderate to severe sexual problems increased from 12.5% in both groups at baseline to 53% and 34% in the CT and EBRT groups, respectively.

At baseline, 113 men reported being potent, and 62% in the cryoablation arm and 55% in the EBRT arm were having unassisted intercourse at that time. At 36 months this had decreased to 22% in the cryoablation arm and 36% in the EBRT group. Overall men treated with EBRT had better sexual function following treatment.

UroToday.com, 26 October 2009

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