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Us TOO[®]
PROSTATE CANCER
EDUCATION & SUPPORT

HOTSHEET

September 2008

SEPTEMBER IS PROSTATE CANCER AWARENESS MONTH!

PROSTATE TEST ADVICE FOR ELDERLY WON'T STOP DEBATE

New advice that men over 75 should not be screened for prostate cancer won't quell the long-standing controversy over the usefulness of the blood test for the disease, cancer experts said last month. "It stokes the debate, I think," said Dr. Charles Ryan, a prostate cancer specialist at the University of California, San Francisco. And several experts are looking ahead to new research that may provide more specific guidance for all age groups.

The US Preventive Services Task Force, a panel of experts who guide national health care, issued its report Monday based on a review of past research. The task force found that screening can detect some cases of prostate cancer, but the benefits of treatment in men over 75 "are small to none." Treatment often causes "moderate-to-substantial harms," including impotence and bladder control and bowel problems, the task force said, without evidence it saves the lives of these elderly men. The panel did not recommend for or against

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FIRST ANNUAL EDWARD C. KAPS HOPE AWARD WINNERS ANNOUNCED

On December 11, 2007, Us TOO announced nominations were open for Us TOO's First Annual Edward C. Kaps Hope Award. Ed Kaps was one of the organizing and founding Board Members, and remains a Director Emeritus of Us TOO International. The Edward C. Kaps Hope Award is given to "An Outstanding Leader in an Us TOO Support Group Who Has Shown Unselfish, Dedicated Service to Prostate Cancer Survivors and their Families."

Any Us TOO International support group volunteer was eligible. By the Feb. 15, 2008 deadline there were a total of 33 nominations. The letters that we received were amazing. The time and effort that men and women put into writing these letters of recommendation was truly heartfelt. In the staff and committee review, the following seven were judged the most outstanding. Two of the nominees are recognized in memoriam. The winners are:

Chuck Maack, Treasurer of Us TOO Wichita, KS
Shirley Grey, Don Johnson Chapter, Palatine, IL

(Continued on page 2)

AMGEN ANNOUNCES POSITIVE RESULTS FOR DENOSUMAB FOR BONE LOSS IN MEN UNDERGOING ANDROGEN DEPRIVATION THERAPY

Data from First Pivotal Study in Men Met Primary Endpoint of Increases in Bone Mineral Density and Secondary Endpoint of New Vertebral Fracture Reduction

Amgen recently announced findings from a three-year pivotal Phase 3 placebo-controlled trial evaluating denosumab in the treatment of bone loss in men undergoing androgen deprivation therapy (ADT) for non-metastatic prostate cancer.

In this study of more than 1,400 men, denosumab treatment produced statistically significantly greater increases in bone mineral density (BMD) at the lumbar spine (primary endpoint) and non-vertebral sites compared with placebo at multiple time points. These improvements in BMD were consistent with those seen in other denosumab studies evaluating BMD in women with

(Continued on page 6)

EDWARD C. KAPS 2008 AWARD WINNERS

(Continued from page 1)

Stan Rosenfeld, Us TOO Marin County Support Group, CA
 Ralph Valle, Us TOO St. Joseph Hospital Support Group, Phoenix, AZ
 Bill Blair, Us TOO Mets Mavericks, Don Johnson Chapter, IL

In Memoriam:

Jack Pais, Us TOO Belgium
 Harry Pinchot, Us TOO Thousand Oaks & Marina Del Ray, CA

The complete nominee's testimonial letters and list of all the men and women who were nominated will be available online at <www.ustoo.org>. We want to congratulate all of the winners and to all of those who were nominated! Us TOO will be presenting Honorary Plaques to all awardees who will be attending Us TOO University in Phoenix at a special "Celebration Dinner" on Nov. 8, 2008. Ed Kaps is planning to be there to congratulate them in person!

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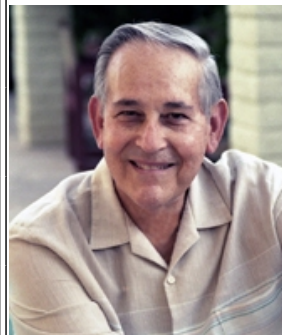
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Shirley Grey



Stan Rosenfeld



Ralph Valle



Bill Blair

IN MEMORIAM



Jack Pais



Harry Pinchot

DO YOU KNOW WHERE YOUR PROSTATE CANCER TISSUE IS?

Joseph D. Khoury, Lou Fink, and Nicholas Vogelzang, MDs

Nevada Cancer Institute, Las Vegas, NV

To make the diagnosis of prostate cancer, surgeons usually biopsy the prostate gland. The biopsy specimen is sent to the laboratory to be examined by another physician, the pathologist. The pathology laboratory prepares the specimen via a number of steps. Ultimately, the tissue is embedded in wax (paraffin), sliced into very thin sections, and placed on a glass slide for examination under the microscope by the pathologist. The pathologist then examines ("reads") the slides and determines whether or not the tissue contains cancer cells.

If the patient and surgeon proceed to a radical prostatectomy, the pathologist follows the same procedures but with the larger specimen. Laboratories are mandated by the College of American Pathologists (CAP) to retain biopsy and surgical material with corresponding reports for a minimum of 10 years.¹ This is also true for many state regulations governing this matter. In the present era where significant advances in the management of certain cancer types have been achieved, this recommended timeframe is falling short of the survival some patients enjoy.²

We have recently reported that some patients with prostate cancer who relapse several years after initial diagnosis are being denied enrollment on some clinical trials because their initial pathology was discarded after 10 years by the hospital or clinic where the initial biopsy or surgery was performed. In fact, in one clinical trial that is currently open at our institution, a 5/28 (17.9%) otherwise eligible patients were denied enrollment *solely* because their initial diagnostic material had been discarded.

Based on (1) our institution's experience that about 1/6 of patients could not enter the trial because they were diagnosed more than 10 years prior to consideration of entry on the trial; (2)

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EARLY FINDINGS CREATE BUZZ FOR POTENT NOVEL HORMONE BLOCKER

Abiraterone, a novel, potent hormone-blocker, appears to be safe for treatment of castration-resistant prostate cancer, researchers here reported. Moreover, results of the 21-patient study suggested that androgens from nongonadal sources may drive progression of prostate cancer in a subset of patients, Johann S. de Bono, MB, ChB, MSc, PhD, of Royal Marsden Hospital, and colleagues reported in a study published online July 21st by the *Journal of Clinical Oncology*.

From December 2005 through February 2007, the single-center study recruited 21 chemotherapy-naive men with prostate cancer that was resistant to multiple hormonal therapies. Median baseline PSA was 46 ng/mL (range 8.8 to 354 ng/mL). At baseline, 17 men had bone metastasis and eight men had soft tissue disease. After a four-week washout, men were given continuous abiraterone at doses ranging from 250 to 2,500 mg.

Antitumor activity was observed at all doses, but, "because of a plateau pharmacodynamic effect," 1,000 mg was selected as the dose going forward in phase II trials Dr. de Bono said. PSA responses were seen in many men, declines of which ranged from 30 to 90%. Five patients remain on the study drug and have "an ongoing clinical response to abiraterone alone; seven patients remain on a combination of dexamethasone and abiraterone acetate."

Abiraterone is a potent, selective, irreversible inhibitor of an enzyme – cytochrome P or CYP 17 – that "catalyzes two independently regulated steroid reactions key to androgen and estrogen biosynthesis," the researchers said. Results of the study, a phase I trial, have received widespread press coverage, where the findings have either been touted as a major breakthrough for advanced prostate cancer or "appalling hype."

An editorial that criticized the press coverage appearing in *The Guardian* (<www.guardian.co.uk>, 23 July 2008). It pointed out that this was a Phase I study, which is done to find out if patients tolerate a drug, if there are any dose-limiting side-effects and the optimal drug dose to use in determining if the drug is truly effective in subsequent large, controlled, randomized trials.

Otis Brawley, MD, chief medical officer of the American Cancer Society, agreed with *The Guardian's* assessment. "All of us in cancer care have seen reports of promising results showing a small number of patients surviving a long time, and once the drug has entered into a randomized trial against a placebo or the current standard of care, the results show no real difference," he said. Although PSA results can indicate tumor activity, PSA is not a definitive measure of response, he noted.

MedPage Today, 25 July 2008

Us TOO Seeks Board Member Applications

Us TOO is pleased to announce the annual public call for nominations to the Us TOO International Board of Directors. The Board Membership Committee, chaired by Fred Mills, will review and evaluate nominees and submit recommendations to the full Board for approval at its December 2008 Board meeting.

Selection criteria includes items such as the candidate's relationship to Us TOO's purpose, its membership criteria ("...any man diagnosed with prostate cancer, a member of such a man's family or significant other, or any person involved in or interested in support or treatment of any such patients..."), familiarity with an Us TOO chapter, ability to think globally, skills or experience deemed beneficial to the work of Us TOO and commitment to Us TOO's purpose and mission.

Letters of nomination with a vita or resume should be sent by August 31, 2008 to Thomas Kirk, President/CEO, Us TOO International, 5003 Fairview Avenue, Downers Grove, IL 60515 or e-mail tom@ustoo.org.

**DENDREON INITIATES
PHASE 2 TRIAL OF
PROVENGE® IN PATIENTS
WITH LOCALIZED PROSTATE
CANCER PRIOR TO SURGERY**

Dendreon Corporation announced that the Company has initiated a Phase 2 trial of PROVENGE® (sipuleucel-T), Dendreon's investigational active cellular immunotherapy for the treatment of prostate cancer, in men with localized prostate cancer who are scheduled to undergo a radical prostatectomy (RP). The single-center trial called NeoACT (NEOadjuvant Active Cellular immunotherapy), or P07-1, conducted at UCSF Helen Diller Family Comprehensive Cancer Center, has begun enrolling approximately 40 patients. NeoACT is the first of two new Phase 2 trials of PROVENGE initiated this year.

Each patient will receive a complete course of active treatment over a one-month period. The course of treatment will consist of three infusions of PROVENGE-two weeks apart beginning six to seven weeks prior to RP. Multiple safety and efficacy endpoints will be evaluated including the immune response in the prostatectomy specimens and in the peripheral blood. Following RP, patients will be randomized to receive either a PROVENGE booster or no booster. Patients interested in additional information about this trial may visit <www.clinicaltrials.gov> and use the search term "NeoACT."

"I am pleased to help lead the NeoACT clinical trial, given the therapeutic potential of immunotherapy for prostate cancer," stated Lawrence Fong, MD, principal investigator of the NeoACT trial and associate professor of medicine at UCSF Helen Diller Family Comprehensive Cancer Center. "This study will provide a unique opportunity to examine the immune response to PROVENGE in actual prostate cancer tissue and to examine the correlation between immune responses in the tissue versus those in the circulating blood."

"Given the evidence of a survival benefit seen in our previous Phase 3 trial in patients with advanced prostate cancer, we believe PROVENGE may also have applicability to men with earlier stages of the disease. This trial will help us better understand the mechanism of

**CONGRATULATIONS TO ALL NOMINATED FOR THE
2008 EDWARD C. KAPS HOPE AWARD (*denotes winners)**

- Jeff Albaugh – Us TOO Northwestern Memorial Hospital, IL
- Bob Boyd – Us TOO Flint, Michigan Chapter
- Gene Bartlett – Us TOO Mobile Chapter, AL
- Bill Blair* – Mets Mavericks, Us TOO Don Johnson Chapter, IL
- Chuck Carlson – Us TOO Southern New Mexico Chapter
- Bert Chamberland – Us TOO St. Lukes Hospital Tempe, AZ Chapter
- Bill Eickelberg – Retired Regional Director WI
- Russ Gould – Us TOO Don Johnson Chapter, IL
- Shirley Grey* – Us TOO Don Johnson Chapter, IL
- Phil Harris – Us TOO Wake County Support Group Raleigh, NC
- Cornelius Harris – Us TOO Hillman Cancer Center & Us TOO Terah Brown, Pittsburgh
- Dick & Dee Howe – Texas Us TOO, Houston, TX
- Robert Horney – Us TOO, Florence, Oregon Chapter
- Dr. Donald Layton – Us TOO Rochester, MN
- Charles (Chuck) Maack* – Us TOO Wichita Chapter, KS
- Jan Manarite – Wife of PCa Survivor, Staff member PCRI, involved w/ Raise a Voice, FL
- Bill McLaughlin – Us TOO, Buffalo, NY Chapter
- Jan Motley – Us TOO Mets Mavericks, Don Johnson Chapter, IL
- Jack Pais* – Us TOO Belgium (deceased)
- Johnny R. Payne – Us TOO Greenville, SC Chapter
- Harry Pinchot* – Us TOO Thousand Oaks & Marina Del Ray, CA (deceased)
- Stan Rosenfeld* – Us TOO Marin County Hospital Chapter, CA
- Craig Schmidt – Us TOO Port Jefferson, NY
- Vanessa Spears – Us TOO Mercy Hospital, Chicago, IL
- Jaren Smith – Us TOO Las Colinas, TX
- Bill Stevens – Us TOO Lancaster, Ohio Chapter
- Judi Sumoski – Us TOO Lancaster, PA
- Richard Swanson – Us TOO Bellevue, Washington Chapter
- Ralph Valle* – Us TOO St. Joseph Hospital Support
- William Woloshin – No Us TOO affiliation
- Roland Young – Us TOO Regional Director & Midlands Chapter, SC
- Rex Zeiger – Us TOO Regional Director Arizona

action and biology of PROVENGE, as well as evaluate the potential of PROVENGE in patients at high-risk for recurrence of their cancer following RP," stated Mark Frohlich, MD, senior vice president, clinical affairs and chief medical officer of Dendreon.

Dendreon Corporation, 16 July 2008


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SCREENING 75-YEAR OLDS

(Continued from page 1)

prostate screening of men under 75 but suggested that doctors discuss the potential benefits and harms of the test with their patients.

"I think it's a very well done and justifiable recommendation," said Dr. Barnett Kramer, associate director of disease prevention at the National Institutes of Health. "They continue to say the jury is still out for men under 75." Prostate cancer screening is done with two tests: a PSA blood test and a digital rectal exam. The test is controversial because the PSA level can be high for many reasons. A positive result from the test must be confirmed by a biopsy. And there's no agreement on the best way to treat it: "watchful waiting," surgery, hormone therapy, radiation or some combination of those.

The American Cancer Society's recommendations for screening doesn't set an age to stop screening but suggests that men shouldn't be offered screening if they aren't expected to live another 10 years, Brooks said "That's because every 75-year-old is not created equal," he said. While some have health problems and aren't likely to live long, others are "very active, very vigorous and have minimal health issues, and many of those men are going to live into their late 80s or 90s," Brooks said.

The Cancer Society's Brooks noted that four major studies are underway on prostate cancer screening and treatment. "Hopefully, within the next three or four years, we will have some outcomes from those studies and be able to give a little more definitive guidance to men and physicians," he said.

Associated Press, 5 August 2008

DEFENDING THE PROSTATE CANCER BLOOD TEST

Given rising medical costs, physicians are increasingly urged to practice "evidence-based" medicine. The recently updated guidelines for prostate-specific antigen, or PSA, screening for prostate cancer ["U.S. Panel Questions Prostate Screening," front page, Aug. 5] illustrate the promise but also the pitfalls of incomplete evidence as well as the importance of individual considerations.

I am a general internist, and, in the past three years, I have known two men (not my patients), one in his 80s, the other in his 90s, who were not screened and who developed florid prostate cancer with multiple painful metastases to their bones. The younger man had other health problems, but his cancer responded to hormone treatment that significantly improved the quality of his remaining years. The older man, otherwise perfectly healthy and in full possession of his faculties, died a painful and almost certainly premature death.

Guidelines are designed for groups and are based on probabilities. Prostate cancer is usually a slowly developing disease. If every man over 75 were screened, and everyone who tested positive were treated, we would be likely to spend more money on prostate cancer than it warrants.

However, the PSA test is easy and cheap. For the two men I mentioned, timely testing could have made all the difference.

Caroline Poplin, MD

The Washington Post, 7 August 2008

EXPOSURE TO AGENT ORANGE LINKED TO PROSTATE CANCER IN VIETNAM VETERANS

New research shows that Vietnam War veterans exposed to Agent Orange have greatly increased risks of prostate cancer and even greater risks of getting the most aggressive form of the disease vs. those who were not exposed. The study's findings are the first to link the herbicide with this form of cancer. The research is also the first to utilize a large population of men in their 60s and the PSA test to screen for the disease. The study was released online ahead of print will be published in the September 15 issue of the journal *Cancer*.

"While others have linked Agent Orange to cancers such as soft-tissue sarcomas, Hodgkin's disease and non-Hodgkin's lymphoma, there is limited evidence so far associating it with prostate cancer," said Karim Chamie, lead author of the study and resident physician with the UC Davis Department of Urology and the VA Northern California Health Care System.

More than 13,000 Vietnam veterans enrolled in the VA Northern California Health Care System were stratified into two groups — exposed or not exposed to Agent Orange between 1962 and 1971. Based on medical evaluations conducted years later, the study revealed that twice as many men exposed to Agent Orange developed prostate cancer. In addition, they were diagnosed 2.5 years younger and were nearly four times more likely to present with metastatic disease.

<<http://www.sciencedaily.com/releases/2008/08/080805092016.htm>>

5 August 2008

Arizona Update

Vital Information You Need to Know About Prostate Cancer

An Us TOO University Patient Education Symposium in the Valley of the Sun



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THE DOCTOR'S NOTE

Gerald Chodak, MD, FACS

Screening is once again in the news as the U.S. Public Health Task Force has issued a report saying that screening for prostate cancer is not appropriate for men over age 75 because the harms outweigh the benefit. This is an important change reaffirming the fact that no studies have shown a benefit from screening and for those diagnosed with the disease, the harms of treatment outweigh any potential benefits. Studies have shown that far too many elderly men are having routine PSA tests as part of a regular check-up, often without any discussion between doctor and patient. Previous reports have said that screening should not be done unless a man is expected to live at least 10-15 years. This report is even more specific by defining a specific age. Of course, there are some healthy men with a long life expectancy who may still decide they would rather be tested. Nevertheless, this change is important because it could keep many men from having to face a diagnosis and treatment that is not in their best interest.

A recent report of the results of a randomized study using Denosumab is very encouraging. It found that this drug can help men with androgen deprivation avoid one of the major side effects of that treatment by actually increasing bone mineral density rather than just preserving it. This also resulted in a statistically significant decrease in bone fractures. If approved by the FDA, this would be the second scientifically proven treatment for castrated men (Zoledronic Acid is the other approved treatment). Should that occur, a debate is likely to develop as to which of the two products is better for patients, something that can't be answered unless the two are directly compared. Whether such a study will ever be done, however, is unclear.

For elderly men with localized prostate cancer, a long-standing debate is whether treatment is necessary and if so, is castration a good option. A report from New Jersey looked at this question and found no significant difference in overall survival or prostate cancer survival. This is an important issue in prostate cancer management

that has never been properly studied.

Unfortunately, this is not a randomized controlled study and therefore one cannot conclude if these findings are accurate findings may or may not be valid. The reasons are that many factors could have contributed to the decision to treat or not treat these patients resulting in considerable biases. That is the reason why randomized studies are performed, to eliminate the uncertainty and reach conclusions that can be trusted. Having said this, it is widely believed that far too many men receive hormone therapy when they did not need it, so a careful discussion is in order for elderly men who are considering this treatment.

Does Agent Orange increase the risk of prostate cancer? This question is addressed in a recent report from California suggesting that men exposed to it were twice as likely to be diagnosed with this disease. Previous reports have had conflicting results and unfortunately, this report still does not firmly answer the question.

Another report hyped in the news recently is based on a very small study of a drug called abiraterone acetate, which works by blocking hormones produced in the adrenal gland. The study had a mix of patients with various stages of the disease and only looked at the effect on PSA, which is not an acceptable outcome measure. The best we can say for now is let the necessary studies be performed to see if this treatment can be useful.

This issue also contains an interesting letter addressing the length of time that biopsy material is maintained by pathology laboratories which traditionally has been 10 years. Given the unusually long natural history of prostate cancer compared to most other cancers, some men may not be able to obtain their biopsy material should they hope to participate in a clinical study if the cancer returns beyond ten years after diagnosis.

The authors suggest that patients nearing their ten year anniversary following their diagnosis may want to obtain the tissue blocks for their possession

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DENOSUMAB

(Continued from page 1)

breast cancer receiving aromatase inhibitor therapy, and in post-menopausal women with low bone mass.

During the 36-month evaluation period, men receiving denosumab experienced less than half the incidence of new vertebral fractures (a secondary endpoint) compared with those receiving placebo, a statistically significant finding. Furthermore, in the denosumab arm there were fewer non-vertebral fractures.

The incidence and types of adverse events observed in this study were generally similar between the denosumab and placebo groups. The most common adverse events across both treatment arms were arthralgia, back pain, constipation, and pain in extremity. Serious adverse infectious events occurred in approximately 5 percent of men receiving placebo treatment as compared with approximately 6 percent of those receiving denosumab.

"This pivotal study in men with prostate cancer demonstrated once again that denosumab increases BMD consistently at all sites measured. We are also excited by the reduction in vertebral fractures, which permits the conclusion that the increased BMD seen in patients receiving denosumab is associated with improved bone strength," said Roger Perlmutter, MD., PhD, executive vice president of Research and Development at Amgen. "We are encouraged by the potential benefit this may represent to prostate cancer patients undergoing ADT for whom bone loss and fractures are serious and under-recognized complications of cancer treatment."

BUSINESS WIRE, 14 July 2008

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ADT DOES NOT IMPROVE SURVIVAL IN PROSTATE CANCER

Primary androgen-deprivation therapy (ADT), used alone instead of surgery or radiation, does not improve survival, over conservative management, in the majority of elderly men with localized prostate cancer. This finding, from an analysis of data from 19,271 men, appears in the July 9th issue of the *Journal of the American Medical Association* (Vol. 300, pp. 173-81, 2008).

The study calls into question the increasingly common use of primary ADT, especially considering its significant adverse effects and cost, say the researchers. The findings contrast those for adjuvant ADT used alongside radiation and/or surgery, which does improve overall survival.

"I think that the bottom line is that primary ADT does not appear to benefit the average man with localized prostate cancer," senior author Siu-Long Yao, MD, from the Cancer Institute of New Jersey, told Medscape Oncology. "It is possible that certain subsets of men such as those with poorly differentiated cancer might derive some benefit, but you must carefully consider and justify the rationale for primary ADT if you are going to proceed with it."

Dr. Yao and colleagues performed an instrumental variable analysis on a population-based cohort of 19,271 men, aged 66 years or older, with

clinical stage T1 or T2 prostate cancer. All the men were covered by Medicare and none received definitive local therapy; 7867 (41%) men received primary ADT, and the remainder were followed with conservative management. The 10-year overall survival was practically identical — 30.2% with ADT vs 30.3% with conservative management (hazard ratio [HR], 1.00; 95% confidence interval [CI], 0.96 - 1.05). The 10-year prostate-cancer-specific survival was also very similar (80.1% with ADT vs 82.6% with conservative management; HR, 1.17; 95% CI, 1.03 - 1.33).

"My conclusion would be that primary ADT does not appear to be a good alternative to surgery or radiation; outcomes appear to be no better than conservative management or watchful waiting," Dr. Yao commented.

"This study further reduces enthusiasm for the use of hormonal therapy in early-stage prostate cancer, and suggests that such treatment, if used at all, should be limited to high-grade disease, as defined by SEER [Surveillance, Epidemiology, and End Results]," commented Martin G. Sanda, MD, from Beth Israel Deaconess Medical Center in Boston, MA, who was not involved in the study. "Their findings of no survival benefit in intermediate- or low-risk disease add to other recent publications that elucidated flaws in hormonal therapy related to its adverse effects on quality of life and cardiac events among men with prostate cancer," he added.

ADT has significant adverse effects and is costly, the researchers point out. Previous studies have suggested a 10% to 50% increase in the risk for fracture, diabetes, coronary heart disease, myocardial infarction, and sudden cardiac death; a 500% increase in the risk for gynecomastia and hot flashes; and a 267% increase in the risk for impotence. In the US, ADT cost \$1.2 billion in 2003 and was the second-highest Medicare Part B drug expenditure.

Dr. Yao and colleagues suggest that clinicians "carefully consider the rationale for initiating primary ADT in elderly patients with T1-T2 prostate cancer."

Medscape, 11 July 2008

PATHOLOGY RETENTION

(Continued from page 3)

that the median survival after diagnosis of localized prostate cancer is over 15 years; (3) that in many cases the only tissue ever available for prostate cancer patients is the original biopsy; and (4) that valuable genetic and pathologic data are available only from such tissue, we have recently recommended to CAP that tissue blocks on cancer patients be maintained longer than currently mandated.³

We have suggested that CAP needs to amend its requirements for retention of laboratory records and materials.² The aim of such an amendment would be to increase the retention time and to institute mechanisms by which patients are involved in the decision to discard their material.

We have proposed changing the mandated requirement to retain tissue from 10 years to at least 20 years, applicable at a minimum to all diagnostic material on patients with cancer. Thereafter, if the cost of increased retention times is a major concern at a particular facility, there should be an effort to find the patient and ask whether they would like to assume ownership of the material so that they can provide the specimens if they are subsequently needed. This is particularly important as predictive biomarkers for survival and for treatment are increasingly being developed for personalized medicine.

The call for change in the requirements for retention of records and materials should be endorsed by the professional organizations including the CAP and should be endorsed by state legislation.

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FROM THE DOCTOR

(Continued from page 6)

just in case it may be needed unless the recommendation changes. Although affecting only a small number of men, why not be prepared?

Finally, if anyone has visited the new prostate cancer educational website, <www.Prostatevideos.com>. I would love to hear your reaction and any suggestions you may have to offer.



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**IMAGING ADVANCE TRACKS PROSTATE CANCER
IN LYMPH NODES**

A new imaging technique, based on an engineered version of the common cold virus, may help doctors detect the spread of prostate cancer to the lymph nodes earlier.

This, in turn, could help guide more effective treatment decisions, said the authors of a study published in the July 11 edition of *Nature Medicine*.

“It would represent a treatment advance in patients for whom outcome is not good,” study senior author Dr. Lily Wu, a researcher at UCLA’s Jonsson Cancer Center, said in a university news release. “This would help improve the prognosis for these patients by letting us find and treat these metastases early. If we can catch the cancer before it invades other organs, we have a better chance to change the outcomes for these patients.”

Patients whose prostate cancer has traveled to their lymph nodes are more likely to have a recurrence. Finding these tiny metastases in the pelvic lymph nodes is key to making future treatment decisions, yet it is also supremely difficult to do with conven-

tional imaging techniques.

Wu and her colleagues engineered a common cold virus armed with a specific “genetic payload” so that it could to travel directly to lymph nodes in mice and to express its payload only in prostate cells.

The payload consists of a protein that can be picked up on PET scans.

Wu and her colleagues next want to combine the imaging technique with treatment, so that a drug contained in the genetic payload could kill the traveling tumor cells.

“I think this is very exciting for many reasons,” said Wu. “We now know we can reach these prostate cancer metastases at an earlier stage than before, and we know we can deliver genes to those cancer cells that produce proteins that can be imaged by PET. Now we will find out how effective this genetic toxic payload is in preventing further spread of the cancer to other vital organs.”

HealthDay News, 15 July 2008

PATHOLOGY RETENTION

(Continued from page 7)

We hope that this letter will educate and motivate you to search out the location of your prostate cancer tissue. You should know whether the tissue is still available or whether it has been or might be discarded.

Perhaps you will want to consider taking custody of the tissue if the 10-year anniversary is approaching. Regardless of the outcome of your search, it will prevent you from saying one day: I don’t know where my prostate cancer is.

References:

1. College of American Pathologists Laboratory Accreditation Program Inspection Checklists.
2. Chodak GW, Thisted RA, Gerber GS, et al: Results of conservative management of clinically localized prostate cancer. *N Engl J Med* 1994; **330**:242-8.
3. Khoury JD, Fink L, Vogelzang N: Call for Revision of CAP-Mandated Requirements for Retention of Laboratory Records and Materials. *Arch Pathol Lab Med* 2008 (in press).

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