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PROSTATE CANCER
EDUCATION & SUPPORT

HOTSHEET

MAY 2010

ASCO STATEMENT ON THE PASSAGE OF THE PATIENT PROTECTION AND AFFORDABLE HEALTH CARE ACT

While ASCO recognizes that there are strong feelings on both sides of this issue, we are very pleased that the newly passed Patient Protection and Affordable Care Act signed into law this week includes a number of things that will benefit cancer patients in the short term and the long term. However, we also recognize that there is still a lot of work to be done, and we will continue our advocacy on those additional fronts.

ASCO is most pleased that the legislation includes guaranteed insurance coverage for individuals participating in clinical trials. ASCO has been at the forefront of this issue for nearly two decades. Clinical trials remain the cornerstone of cancer research, and are often the patient’s best option. Under the new federal law, patients can now afford to participate.

ASCO also supports closing the drug prescription gap in Medicare Part D. As more and more cancer drugs become available in oral form, the drugs have become less affordable for cancer patients. Beginning in 2010, seniors who fall in the “doughnut hole,” or, spend between \$2,700 and \$6,154, will re-

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A TREATMENT FOR PROSTATE CANCER “INADEQUATE” IN OVER HALF OF ALL CASES

A technique that involves injecting radioactive seeds into the prostate to kill cancer may deliver an inadequate radiation dose to the prostate more than half the time, according to a doctor who trains physicians in the procedure.

“Based on what’s been published over the last ten years, I’d say as many as 50 percent of patients in the US get an adequate implant,” says Nelson Stone, MD, a urologist and clinical professor of urology, radiation oncology and oncological sciences at Mount Sinai Medical Center in New York City.

Dr. Stone, who is also medical director of Prologics, a company that operates and services radiation treatment (RT) centers in the US, believes a careful review of the medical literature suggests that this life-saving procedure isn’t working as well as it should. In brachytherapy (BT), doctors typically use an ultrasound to guide the placement of tiny radioactive seeds into the prostate. Once there, radiation emitted from the implants can eliminate cancers growing in the organ.

While highly effective if used properly, errors can be disastrous. Seeds intended for the prostate that miss

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POSITIVE TEST FOR SANOFI PROSTATE CANCER DRUG

A new drug being developed by Sanofi-Aventis extended the lives of men with advanced prostate cancer in a clinical trial and could become a new last-ditch treatment, researchers reported Wednesday.

Men whose cancer has spread beyond the prostate gland are usually treated with drugs that reduce the body’s production of testosterone, a hormone that can feed cancer growth. When such therapy fails, the only approved option now is the chemotherapy drug docetaxel (Taxotere®), sold by Sanofi-Aventis, but that often fails as well.

The new chemotherapy drug, cabazitaxel, would step in when Taxotere stops working. It was tested in 755 men from 26 countries whose cancer continued to progress despite use of Taxotere.

In the clinical trial, men who received cabazitaxel lived a median of 15.1 months, compared with 12.7 months for those who received another cancer drug, mitoxantrone, a difference that was statistically significant.

Although mitoxantrone is not approved as a treatment for advanced prostate cancer, researchers said they believed it would be more ethical to

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PSA & THE PSA TEST: WHAT THE PUBLIC NEEDS TO KNOW

James Mohler, MD

Senior Vice President for Translational Research
Chairman, Urology Department, Roswell Park Cancer Institute

On March 22nd, National Public Radio ran a segment ("Prostate Test: Lifesaver or Big Mistake?") on its "Morning Edition" program on prostate-specific antigen (PSA) and the controversy regarding the PSA test as an effective screening tool for prostate cancer. Richard J. Ablin, PhD, a research professor of immunobiology and pathology at the University of Arizona College of Medicine, was interviewed for this segment.

On March 10th, the New York Times ran an Op-Ed piece ("The Great Prostate Mistake") written by Dr. Ablin. The take-home messages from these highly reputable news sources are that Dr. Ablin "discovered PSA in 1970" and by virtue of that discovery, would be the obvious reigning authority on the use (and purported overuse) of the PSA test.

Prostate-specific antigen (PSA), a protein produced by the secretory epithelial cells of the prostate gland, is present in small quantities in the blood of normal men, and is often elevated in the presence of prostate cancer and in other prostate disorders. One should not confuse the current PSA with the "prostate-tissue-specific antigens" or proteins (the human prostate contains hundreds of proteins) that were discovered in the early 1970s.

Although Dr. Ablin did indeed discover a "prostate-specific antigen" that is confined to the normal prostate, he neither developed the PSA test nor discovered the PSA that the current test is based on.

That credit goes to Roswell Park Cancer Institute researcher T. Ming Chu, PhD, DSc, who, with an extraordinary team of over 20 researchers, including urologists and pathologists, discovered what the American Association for Cancer Research would later call one of the "landmark scientific discoveries of the 20th century."

Working with human prostate tissue from cancer and benign prostatic hyperplasia, Dr. Chu and his colleagues

identified and purified PSA and later developed the simple PSA blood test that is used today for the early detection and management of prostate cancer.

The team published their first major paper in 1979 in *Investigative Urology*, followed by a 1980 paper in *Cancer Research* that used the PSA test to demonstrate PSA in the blood of prostate cancer patients. Subsequent papers published by the Roswell Park researchers appeared in *Cancer Research*, *Journal of the National Cancer Institute*, *Methods in Cancer Research*, and *Journal of Urology*, among others. A patent was issued in 1984 to the state of New York and Roswell Park Cancer Institute, and the technology was transferred to the biomedical industry for preparing testing kits. The PSA test received FDA approval in 1986 as a monitor for treatment response and disease recurrence, and in 1994, as a screening tool for diagnosis. Since then, an estimated one billion PSA tests have been given.

In recognition of his many contributions to the field of urology, Dr. Chu received the Presidential Award from the American Urological Association in 1993 and was featured in the April 15, 1998 issue of *Cancer Research* for his seminal research on the use of tumor cell products in the diagnosis and treatment of cancer, and for his leadership role in the discovery of PSA and the development of the PSA test.

Is the effectiveness of the PSA test no better than a coin toss, as Dr. Ablin contends in his recent remarks to the media? Let's look at the facts. PSA has revolutionized our ability to detect prostate cancer in its early stages and monitor its course of treatment. Prior to the development of PSA, only 4% of men diagnosed with prostate cancer could be cured. Most were diagnosed with prostate cancer when it had spread to their bones and caused pain. The standard treatment was androgen deprivation therapy and the mean survival was three years. The develop-

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CARBITAXEL

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compare the new drug to an active cancer medicine rather than to a placebo. The trial, in which all patients also received the steroid prednisone, was sponsored by Sanofi-Aventis.

The drug represents “a new therapeutic option for these patients who are very difficult to treat,” Dr. Oliver Sartor, a professor at Tulane Cancer Center and lead investigator of the trial in North America, said Wednesday in a telephone news conference.

He said that about 15,000 to 20,000 American men with advanced prostate cancer were now treated with Taxotere each year, but that 27,000 Americans died each year of the disease.

The trial results were presented in March at the 2010 Genitourinary Cancers Symposium in San Francisco, a conference sponsored by three medical groups (ASCO, ASTRO and SUO).

Sanofi-Aventis said it hoped to complete its application to the Food and Drug Administration for approval of the drug in the first half of this year. Presuming it won approval, that would allow the drug to reach the market by late this year or early next.

Cabazitaxel did have a serious side effect. It depleted infection-fighting white blood cells and led to fever in 7.5 percent of patients, compared with 1.3 percent in those who got mitoxantrone. Cabazitaxel is a taxane, a class of drug that also includes Taxol, sold as a generic as paclitaxel, and Taxotere, also known as docetaxel.

Cabazitaxel was developed to work in cancer cells that had become resistant to other taxanes.

Abstract 9, presented at the 2010 GUCCS, 5 March 2010

New York Times, 3 March 2010

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CHAPTER NEWS!

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INFERTILITY AND PROSTATE CANCER MAY HAVE COMMON CAUSE

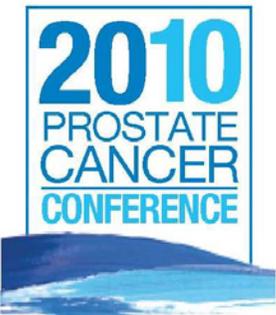
Infertile men could be at increased risk of developing high-grade prostate cancer, but more work is needed, according to a new study published online 22 March 2010 in the journal *Cancer*. Previous studies using the number of offspring sired as a surrogate marker for male fertility have produced conflicting results related to this association.

Dr. Walsh and colleagues examined prostate cancer rates in men with proven male-factor infertility. The study examined data from 22,562 men evaluated for infertility from 1967 to 1998 in 15 California infertility centers. The prostate cancer incidence in these men was compared with that in a

sample of men who were of similar ages and from similar geographic locations. The researchers identified 168 prostate cancer cases in the men evaluated for infertility, a rate not significantly different from that expected in the general population (185 cases).

However, men who had been evaluated and found to be infertile were 2.6 times more likely to be diagnosed with high-grade prostate cancer than men evaluated but not found to be infertile. According to Dr. Walsh, “this suggests that we may want to search for common etiologies that underlie both male-factor infertility and prostate cancer.”

Dr. Walsh suggested that the most clar-



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BRACHYTHERAPY “INADEQUATE” IN OVER HALF OF CASES

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might end up in the bladder, urethra or rectum. There, the seeds could cause serious RT-induced injury. According to Dr. Stone, botched procedures can result in anal bleeding, fistulas and urinary incontinence. Worse than the direct side effects, though, is that radioactive seeds lodged outside the prostate can't fully expose the cancers to RT, which can lead to cancer recurrence, according to Dr. Stone.

After looking over the relevant literature for an upcoming article, Dr. Stone concludes these serious medical errors are startlingly common. As Dr. Stone explains, the success of a procedure is generally determined by a post-implant dosimetry study to measure how much of the RT dose was delivered to the prostate, and how much to outlying areas. In this, the key metric is the D-90, or the RT dose to 90 percent of the prostate. “That number, the dose to 90 percent of the prostate, has been highly correlated with the cure rate, in terms of eradicating prostate cancer,” Dr. Stone says.

Typically, a minimum D-90 for the most common isotope used (¹²⁵I) should be 140 Gy. This dose is held as the benchmark to achieve for controlling cancer, according to Dr. Stone. But in his research he has discovered that as many as 50 percent of the BT procedures performed in the US fail to reach 140 Gy. This means that one half the patients may be getting too low a dose. “Furthermore, these data are derived mostly from academic centers, not community hospitals where the majority of the procedures in the US are performed,” Dr. Stone notes, so the true rate of inadequately performed procedures could be higher.

Evidence of botched BT procedures is not quietly lingering in the pages of medical journals; it has begun to make headlines. Last week, the University of Pennsylvania admitted in January a man undergoing BT to treat prostate cancer had seeds that missed the prostate. The error hearkened back to similar bad news Penn received last summer, when the New York Times uncovered a troubled Penn-administered

BT program at the Philadelphia Veterans Administration hospital. According to the Times, over a six-year period a doctor there bungled 92 out of 116 BT procedures.

And in March 2010, the US Nuclear Regulatory Commission, which found around eight violations during their initial investigation of the hospital, including the VA's failure to properly train personnel to identify and report problems, announced a proposed \$227,500 fine against the VA, the second largest the agency has ever proposed for a medical error.

Echoing the NRC findings, Dr. Stone believes the problem is one of lack of training. “There are no certifications for any of the new procedures out there,” he notes. In learning how to use a new technique, such as prostate BT, most doctors attend a seminar, then go back to their hospital and begin to practice it after only one or two supervised procedures, Dr. Stone says.

“When I was in medical school, the axiom for learning was *See one, do one, teach one* he notes. “You see a procedure, you do one, and then you can teach one.” But now Dr. Stone believes that model is outdated. “Today, procedures are so complicated that no longer fits,” he argues. And when doctors stick with this traditional method Dr. Stone believes patients “suffer the learning curve of the physicians.”

Currently, for prostate BT, the field is only regulated by hospital bylaws, which Dr. Stone believes are inadequate. “Unfortunately, the hospitals are not really equipped to understand what is necessary to make physicians proficient,” Dr. Stone argues.

What Dr. Stone believes works is rigorous hands-on training. And over the last 15 years, Dr. Stone says he has trained around 1,500 physicians world-wide in prostate BT, including around 10 percent of all doctors in the US and close to 75 percent of all Japanese physicians who perform that procedure. Dr. Stone and his colleagues have published on the success of this training methodology.

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ASK DR. SNUFFY MYERS

Editors' note: In the spirit of information sharing, we have invited certain physicians and others to provide comments and opinions for Us TOO's *HotSheet*. It is our desire to enrich the content of the *HotSheet* to empower the reader. Each piece contains the opinions and thoughts of its author and is not necessarily those of Us TOO International.

Dear Dr. Myers,

Are men ever cured by chemotherapy?

This is an interesting question. In the field of medical oncology, we tend to speak of median survival – how many months until half the patients have died. I tend to be less interested in that specific number, but rather the whole survival curve. Why? Because for most treatments of advanced cancer, there are a small group of patients who do much better. It is important to be able to offer patients the hope that they may make it into that favorable group. With Taxotere, the most widely used chemotherapy agent, somewhere between 10-20% of the patients is alive 30-36 months after chemotherapy starts.

So, among those patients, are any cured? The answer is that would be rare. In my whole career, I have seen only one patient who is a candidate for cure. He had a Gleason 10 prostate cancer with a PSA doubling time of 2-3 weeks. He failed hormonal therapy within seven months. He then received 5 months of Taxotere and at that point was in complete remission. That was in April of 2003. We stopped hormonal therapy in April of 2004. His cancer has never returned.

Because his cancer grew so rapidly, it is tempting to think that it would have returned if any cancer cells had survived treatment. Unfortunately, there is a phenomenon called “cancer dormancy.” Cancers can remain silent for more than 20 years and then suddenly activate. So, at best, we can only say he is in a durable complete remission.

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PSA & THE PSA TEST: WHAT THE PUBLIC NEEDS TO KNOW *(Continued from page 2)*

ment of the PSA test has completely changed the demographics of newly-diagnosed prostate cancer patients. Less than 10% of American men are diagnosed with incurable prostate cancer today, and the five-year survival after treatment is essentially 100%. In addition, one British study has shown that the prostate cancer mortality rate in the USA for the period of 1994 through 2004 had a rate of decline greater than four times that of the United Kingdom, where the PSA test was not widely used.

As the pioneer of the PSA test, Roswell Park Cancer Institute has been in the frontlines of the recent national discussion on the challenges and value of mass prostate screening using the PSA test. Two Roswell Park faculty members, including myself as chair, serve on the National Comprehensive Cancer Network (NCCN) Guidelines Panel for Prostate Cancer, the group that develops the national/international

“best practice” guidelines. On March 4, I was invited to give expert testimony at an important hearing (“Prostate Cancer: New Questions About Screening and Treatment”) before the House Committee on Oversight and Government Reform. My testimony, I believe, provided some clarification as to why the PSA controversy continues to be waged.

For example, the incidence of prostate cancer if one autopsied the prostate is approximately the age of the man. In other words, 20% of 20 year olds already have cancer in their prostate and 80% of 80 year olds have prostate cancer. Prostate biopsies will find about 1/2 of these autopsy cancers. Thus, 40% of 80 year olds and 10% of 20 year olds will be found to have prostate cancer if their prostates are biopsied. Because PSA can be elevated for many reasons, many men who undergo prostate biopsy may have an autopsy-type prostate cancer

diagnosed rather than one that poses a threat to their life expectancy.

There is legitimate concern that widespread use of the PSA test may over-diagnose prostate cancer and put men at risk for complications from unnecessary treatments such as surgery and radiation. But it’s not the use of the PSA test that’s at the root of the national debate – it’s deciding what to do with the information it yields.

Indiscriminate use of PSA and aggressive diagnosis and treatment of prostate cancer is unlikely to significantly impact the survival of American men and may adversely affect the quality of life of American men. The NCCN has responded by changing the 2010 Guidelines to focus on a more careful detection of aggressive prostate cancer in younger men while urging a more conservative approach to early detection of prostate cancer in older men; NCCN recommends that attempts to

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ASCO STATEMENT

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ceive a \$250 government subsidy to help cover the costs of their medication. By 2020, Medicare will cover 75 percent of drug costs in the “doughnut hole” for Medicare patients.

The removal of lifetime caps on insurance coverage is also a step forward for cancer patients. Many cancer patients who need repeated courses of treatment can easily exceed their caps and find themselves unable to afford needed treatment and medication. ASCO looks forward to seeing the financial burdens often associated with cancer treatment ease under this new federal policy.

Children with cancer will also benefit from the legislation. In just six months, insurers will no longer be able to exclude children with pre-existing conditions from being covered by their family policy. For current policies, that means insurance companies must rescind pre-existing condition exclusions. ASCO is also pleased that dependent children up to age 26 will be able to remain on their parents’ family policy effective immediately.

While ASCO supports improved access to healthcare for millions of Americans, uninsured cancer patients still won’t have sufficient coverage. These patients cannot afford to wait. ASCO is ready to work with policy-makers and the Obama Administration in order to fill this urgent gap.

ASCO is also deeply concerned that the legislation does not address the flawed Sustainable Growth Rate. Oncology practices are struggling to survive, and ASCO urges a permanent repeal of the SGR. The temporary patches implemented in the past are no longer a viable solution. The SGR could potentially cause devastating cuts that will negatively impact cancer patients and practices; immediate action must be taken.

ASCO, representing more than 28,000 oncologists, will continue to support public policy that ensures patient access to high-quality cancer care and supports increased clinical cancer research.

For more information, please contact Amanda Stanley, (571) 483-1364 or <amanda.stanley@asco.org>

DOC MOYAD’S WHAT WORKS & WHAT IS WORTHLESS COLUMN, ALSO KNOWN AS “NO BOGUS SCIENCE” COLUMN

“Provengé® is supposed to be FDA approved by the time you read this column! So, I am going on strike/boycotting my own column!”

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

Editors’ note: In the spirit of information sharing, we have invited certain physicians and others to provide comments and opinions for Us TOO’s *HotSheet*. It is our desire to enrich the content of the *HotSheet* to empower the reader. Each piece contains the opinions and thoughts of its author and does not necessarily reflect those of Us TOO International.

Bottom Line: After almost a decade of research and debate the FDA should approve Provengé for men with hormone refractory prostate cancer (HRPC) by 1 May 2010. So, in deference to this important decision I am boycotting my own column!

I was going to write a column on an anti-stress amino acid compound found in tea called “L-theanine.” Instead, I am going to have a cup of green tea with L-theanine and simply boycott my column this month! I am taking a stand!

I was going to tell you that L-theanine from tea, especially green tea, or L-theanine dietary supplements now have plenty of evidence that it increases the level of anti-stress compounds in the brain without causing drowsiness. So, L-theanine can reduce your stress and keep you alert and it does not increase blood pressure or heart rates from clinical studies so I was going to tell you that L-theanine is heart healthy! In fact, L-theanine has been used in Japan in over 50 food products including chocolate and chewing gum since the 1960s.

However, I am not going to continue to write my column this month until the FDA approves the Provengé immune therapy personalized vaccine for men with HRPC. In other words, by the time you read this column, Provengé is suppose to be approved by the FDA! If the FDA does not approve Provengé by the time you read this column in May, I will cease to plug in my computer and write!

Some folks go on hunger strikes to get what they want, but I did not want to lose weight! Others go on a work strike, but I did not want the University of Michigan or my family to suffer. Some people stand on high buildings with signs until the police come and get them, but in Michigan it is still really cold outside, and I am not fond of prison food, striped clothing, or a mug shot that includes my profile (have you seen how big my nose looks when I am standing sideways-ouch!).

So, I decided to take a stand in the only way that I can take a stand. I am going to drink several cups of green tea daily to get plenty of L-theanine, so I am not stressed (yet still alert and attentive), and then I am going to boycott my computer key buttons and email delivery system to Us TOO in the next few seconds.

So, the FDA should approve Provengé by May 1, 2010 and if they do or do not approve Provengé this time, let me tell you what I really think about the FDA, they are the most....oops sorry, the boycott has begun and I will finish this sentence next month!

Reference:

Me=Mark A. Moyad, MD, MPH – at home 7:10 AM with 8 ounces of green tea in my left hand and 1/3rd cup of All Bran cereal in my right hand on 1 April 2010.



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DOCTOR CHODAK'S BOTTOM LINE

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It seems that not a month goes by without someone saying something good or bad about the PSA test and its role in screening. Dr. Mohler has written an article to alert readers about comments made by Dr. Richard Ablin in the New York Times. Ablin claimed to be the discoverer of PSA and then heavily criticized the test. As Dr. Mohler correctly explains, the PSA test in use today was not discovered by Ablin which makes some of his criticisms lose value. But he is correct in his concern that many of the men diagnosed have not benefited. Still, the PSA has truly been revolutionary in helping many men with prostate cancer.

But then we get back to the question of its role in screening. Dr. Mohler is partly correct in stating that the screening test is not the problem, it is what is done with the results. That is not entirely correct. The fact is that the public has been misled about PSA. For 20 years, people have been told that screening will save their lives without the proof to support it. Lacking has been a balanced message of the risks and benefits of screening. Men of all ages and health status have been screened without knowing it and without having a choice.

We now know that screening does save lives but at a large risk of over treatment. To address that problem, the NCCN is recommending that men with very low risk cancer go on Active Surveillance if their life expectancy is less than 20 years. The problems are that most doctors will not follow that approach, many men will have difficulty accepting it and the results with active surveillance are less than ten years old.

The Bottom Line: As recommended by the American Cancer Society, all

men should be informed of the risks and benefits and then decide whether to be screened. Once diagnosed, all men should be informed about the risks and benefits of Active Surveillance along with the other treatment options. A large percentage of men diagnosed today will never need to be treated.

The article by Dr. Stone is likely to raise serious concern among men treated by brachytherapy. He claims that 50% have been under treated because of improper technique. This may result in incomplete treatment of the cancer. It also may mean that seeds will end up in the bladder, urethra or rectum leading to serious problems such as anal bleeding, fistulas and urinary incontinence. His concern is that many physicians who do brachytherapy may not have been adequately trained and supervised. A survey of Medicare patients from the 1990's does show higher complication rates compared to academic centers but it is not possible to assess if they have a higher rate of recurrence.

What does this mean for those men already treated by brachytherapy or those considering the treatment? First don't panic. Fortunately, many of the men treated probably had low risk cancers anyway so they have little danger. Those with intermediate risk cancers (Gleason 7, PSA greater than 10 ng/ml) treated at non-University centers may want to contact their doctor and ask for their postoperative assessment to see if they received the 140 Gy recommended. If they did not, then a consultation with another specialist may be worthwhile.

The Bottom Line: Men considering brachytherapy should find out the training, experience and results of the physician who will do the treatment to help ensure they will be treated properly.

Lastly, more encouraging news about men with advanced disease. A new drug called Cabazitaxel is showing promising results and may be the next step for men no longer responding to

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BRACHYTHERAPY

(Continued from page 4)

When asked why the Japanese seem so eager to absorb his training, Dr. Stone attributes it to differences in medical culture between Japan and the US.

In Japan, the health system is partly nationalized. Doctors are directly salaried by the hospital, according to Dr. Stone. "They all get paid the same salary and work the same hours. There's a different philosophy when it comes to the approach to medicine," he says.

But all is not entirely rosy. Although the Japanese are believed to have lower rates of prostate cancer, Dr. Stone says once diagnosed three-fourths of Japanese men have advanced disease, which is more likely to be fatal.

"The reason is they have no early detection program," he says. "There's no PSA [Prostate-Specific Antigen test] screening, whereas in America it has been going on since 1990." In the US, Dr. Stone says more than 80 percent of men will have had their PSA levels checked by the time they turn 57. This in turn means when cancer is discovered, it is usually smaller and more susceptible to treatment and cure.

In fact, in America, the mortality rate from prostate cancer has declined over the last five years. "It used to be 42,000 deaths [a year], now it's 27,000," says Dr. Stone. But in Japan, the outlook is grimmer.

<www.DotMed.com>, 26 March 2010



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PSA & THE PSA TEST

(Continued from page 5)

find prostate cancer end when a man's life expectancy falls to <10 years.

The NCCN 2010 Guidelines also recommend active surveillance of men who were found to have low risk prostate cancer when life expectancy is <10 years. In addition, the NCCN has created a new prostate cancer risk category, very low risk prostate cancer; active surveillance is the only recommended treatment in this group of men when life expectancy is <20 years. These changes allow appropriate aggressive treatment of men who are at high risk of prostate cancer death and avoids overtreatment of men at low risk of prostate cancer death.

At Roswell Park, we continue to build on the milestone contributions of Dr. Chu and his colleagues. Our research is focused on developing a better PSA test, one that will distinguish aggressive, life-threatening prostate cancers from those that are slow-growing and not life-threatening so that appropriate treatment decisions can be made.

The need for a more precise early detection tool is both challenging and urgent. On this point, we are all in agreement.

INFERTILITY AND PROSTATE CANCER *(Continued from page 3)*

ity will come from studies that identify risk factors for male infertility.

"Subjects assembled for such a study could then be followed longitudinally, with standardized prostate cancer screening, to determine if they develop prostate cancer or not" he said.

"We were surprised to find significant risk only for high-grade cancers," Dr. Walsh added. "This fact alone raises many questions... What are the etiologies that may lead some men to have poor sperm production early in life and high-grade cancer later in life? Could this association be translated into a tool to identify men who are at greatest risk for dangerous cancer?"

Aleksander Giwercman, MD, professor of andrology at Malmö University Hospital's Scanian Andrology Center in Sweden, commented on this study. "I think that the study has some limitations," he said "First of all, the use of a white population as the control group is questionable for me. The risk of prostate cancer is highly race-dependent, and it is also likely that testicular function – and therefore semen quality – may differ between races. Therefore, not strictly controlling for race in matching the cases and the controls may introduce a serious

bias that, theoretically, could affect the risk-ratio estimates in both directions."

Dr. Giwercman also pointed out that the researchers had complete data on less than 50% of all subjects. "This could also be a source of serious bias, as cancer data were, apparently, not available for half of the men," he said.

Medscape Medical News, 25 March 2010

THE BOTTOM LINE

(Continued from page 7)

Taxotere. As with any chemotherapy, serious side effects can occur but not very often. It is hoped that this drug will receive FDA approval. On a side note, it is a concern that many of the men who die from prostate cancer never received Taxotere despite the fact that it improves survival in men with hormone refractory metastatic disease. Too many men are never even informed that it is an option.

The Bottom Line: All men with metastatic prostate cancer should have a discussion with an oncologist about the pros and cons of chemotherapy when they begin to progress on hormone therapy.

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