Prostate Cancer Support Association of New Mexico

LIFELINE

PCSA Quarterly Newsletter October 2012 Volume 19, Issue 4

Issue Highlights

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Thanks We thank all of you who have made contributions to the organization to help keep us running. You can also designate donations through the United Way in the fall.

From *PCRI Insights* • August 2012 Summary by Dave Ball

Newly Diagnosed Prostate Cancer: Understanding Your Risk

When the urologist calls with the life-changing news that your prostate biopsy is positive for prostate cancer, an office appointment is made to discuss your options. This article will help you understand the new medical terms and jargon introduced at the newly diagnosed interview. Learn how your medical diagnosis details are applied to risk assessment tools to predict if you have low, intermediate, or high risk prostate cancer. Understanding your risk will guide you to making informed treatment choices.

- Most men newly diagnosed with prostate cancer will go on to live a normal life span.
- Many prostate cancers are Low-Risk, slow-growing and not very dangerous. Often, treatment can be safely delayed for years by following Active Surveillance, or relatively non-toxic treatments can be chosen. That avoids or delays possible treatment side effects such as impotence or incontinence.
- A few newly-diagnosed men have High Risk prostate cancer that is aggressive and potentially life-threatening. Those men may benefit from more aggressive therapy. They may accept the side effects risks in hopes of eradicating, or at least controlling their high risk prostate cancer.
- Men with Intermediate Risk prostate cancer have the hardest treatment choices. Their risk may be a little too high to be comfortable with Active Surveillance, while at the same time not being high enough to clearly indicate for aggressive therapy with its risks.

Obtain Your Medical Records

The clues to a man's prostate cancer risk (and his eventual treatment choice) can be found in his clinical diagnosis medical records. One cannot understand his prostate cancer risk level without obtaining and understanding his medical records. Sometimes, a doctor's office is not set up to easily provide patients with copies of their records, and some additional 'prodding' may be needed to obtain the copies. During the initial diagnosis office visit, the doctor will have your medical records chart on hand. This is a good time to ask for copies. A man has a right to his medical records, but a reasonable copy fee may be charged. Obtain the following records:

1. PSA History. Make a log with the dates of all your PSA tests. Note any special events, such as "Suspicious Digital Rectal Exam (DRE)" or "Biopsy Ordered".

2. Urologist's Notes that discuss the Clinical Stage from the Digital Rectal Exam (DRE), for example, T1c or T2b.

3. Ultrasound Report (TRUS) from the biopsy. This is written by the urologist, and lists the size of the prostate in grams or cubic centimeters (cc). It may also indicate other risk factors.

4. Biopsy Pathology Report. For each core, learn the Gleason Score, extent of disease in the core, and other important clinical diagnosis information.

(Continued on page 5)

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In Memory of

With Deep Sympathy and Regret, We List These Names

Derald McPherson

Robert E Rogers

Eloy Moya

PC SUPPORT GROUP MEETINGS

Support Meetings are usually held on the first and third Saturday of each month at 12:30 PM. We meet at the Bear Canyon Senior Center, located at 4645 Pitt NE (on Eubank go one block north from Montgomery - Right (East) on Lagrima De Oro - Left (North) on Pitt to Senior Center).

Please call ahead to verify time and dates. 254-7784 or (800) 278-7678; or check website or Facebook page.

PCSA *Lifeline*

A quarterly newsletter addressing issues of prostate cancer

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MEETINGS
Lou Reimer

DISCLAIMERS

The PCSA of New Mexico gives education, information and support, not medical advice. Please contact your physician for all your medical concerns.

Dr. Lindberg's Take

Dr. Peter Lindberg

Northern New Mexico Cancer Care Office: (505)661-9165

July 19, 2012 The New England Journal of Medicine published an important clinical trial: Radical Prostatectomy versus observation for localized prostate cancer. After 10 years median follow-up radical prostatectomy-"getting it out of there"- did not reduce death from prostate cancer or all-cause mortality. The absolute differences were less than 3%. In detailed analysis, surgery did reduce all-cause mortality in men who had a PSA greater than 10 at the time of diagnosis. Also a radical in men with intermediate and high risk disease produced a somewhat lower death rate but this did not reach statistical significance.

In an accompanying editorial Ian Thomsen, a urologist from the U. of Texas challenged the author's conclusions, mainly on the basis that the clinical trial only had 753 men when it should have had 2000 men enrolled. Therefore not enough numbers to prove the above conclusions or even to show a 25% difference in cancer mortality.

My understanding is that this study supports the approach of active surveillance in men with low risk cancer--PSA of less than 10, small or no lump and a Gleason score of 6 or less. For my men in this category, I send many to Duke Bahn in Ventura, California for color-Doppler ultrasound of the prostate. Duke's accuracy has recently been confirmed by the folks at M D Anderson hospital. One of their patients was seen by Duke and also in Houston. They confirmed his accuracy. I realize many urologists dismiss this, but Duke is on the national Board that sets the standards for cryo therapy, on the faculty of the U. of Southern California in the Dept. of Urology, and has been doing many thousands of these exams, most HELPFUL to my patients. Another approach to looking at the prostate to find more extensive cancer is an endorectal prostate MRI, possibly at the U. of New Mexico. Finding a lot of cancer suggests a need for radiation or an RP.

In men with high risk, life threatening prostate cancer (PSA >20 or Gleason 8, 9, or 10, or a very large tumor mass) there is good evidence that lupron or other drug in this category AND Casodex or other drug in this category improves survival. Shots alone are not adequate therapy. I use triple hormone therapy® along with radiation. In 30 men, were 2 early PSA failures and 2 other late failures in men who did not take all their medications. For some high risk men a radical or a radical+radiation may be as good an option.

On August 10, 2012 from the European Journal of Urology, an analysis of 76,500 cases from the Swedish national tumor registry gives some backup for the New England Journal cancer trial. In men who were in excellent health except diagnosed with low risk prostate cancer, there was no difference in all cause death rate between treated and observed men. Death rates in the intermediate risk were only slightly greater in the not-treated group. For men with high risk group, especially men under 65, there was a substantial benefit for active treatment. The death rate from prostate cancer was 10 times greater in the high vs. low in the observation arm. Not stated but I think the treatment usually is surgery. Causes of death other than prostate cancer were strongly related to initial health as measured by the Charlson Co-morbidity Index score. As usual, there are no simple answers in prostate cancer.

Correction to the last article I wrote. Six-6- Avodart tablets+ lupron before surgery was equal to Lupron+ Casodex or Lupron+Casodex+Ketoconazol in suppressing Dihydrotestosterone in the cancer when given before surgery. This was just a small trial, but perhaps 6-six- Avodart could be added to other agents to treat prostate cancer if a large clinical trial proved effectiveness.

We would really like to encourage more of our members to sign up for our weekly--and we mean only ONE per week-- emails. You get meeting announcements and information on the program speakers. You can also forward it to family, friends, coworkers. We send other timely news information that does not make it into the newsletter, because it is too big or it has just been published. Just call or email the office-- the address and phone # are on page 2--to get yourself or family/friends on the email list. And don't forget to check our website often www.pcsanm.org and read our 2 news pages: Our Latest Newsletter and News You Can Use. And we welcome your news, information, websites, articles, which we could share with others.

Men: What is your PSA?
This simple blood test can give you warning of Possible prostate problems, especially cancer,
Make an appointment for a low cost test on
Saturday, October 6, 2012
(Between 9:00 AM and 12:00 Noon)
at the Bear Canyon Senior Center
(4645 Pitt NE., ABQ,
near Montgomery & Eubank)
Cost is $20 payable at the door
(cash or check only)
Appointments required Call 505-237-8322
Sponsored by: The Prostate Cancer Support Association of New Mexico
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Meet two of our newest Board Members

Joe Piquet

I'm a native New Yorker, born(1936) and bred in Harlem, NY Spent four years in the Air Force where I was trained as a radio operator and re-trained in Air Traffic Control, upon returning from my tour of duty in South Korea. I was stationed at Andrews AFB until being discharged. I served from 1955 to 1958. I am a retired government employee, after serving in the Federal Aviation Administration (FAA) and Social Security Administration (SSA).

I ran my own printing business for 10 years until selling the business in 1994. I graduated from TVI with an Associate degree as a para-legal.

I was diagnosed with prostate cancer in May 2007, and had Brachytherapy (seed implants) in November 2007. I attribute my knowledge of prostate cancer to the PCSA group in Albuquerque, from the information acquired in the PCSA office and from the many good cancer survivors I've met attending the monthly meetings at Bear Canyon Senior Center.

I am married, I have a married son in Florida, a grand-daughter attending medical school in Tampa, FL, and a married step-daughter in New York.

Dave Ball

David was first diagnosed with prostate cancer in December, 2008 and was treated with external beam radiation therapy. The cancer reoccurred in the first quarter of 2011 and David went through nine months of triple hormone therapy. He completed the hormone therapy in March, 2012 and he now has a very low PSA and is in good health. David's goal is to make available to others diagnosed with prostate cancer the same outstanding assistance and resource information he received from the PCSA. This helped him make informed decisions on effective prostate cancer treatments for himself.

David retired in January, 2008 after 40 years working for the government and private industry as an Engineer and Project/Program Manager. David's career included managing nuclear weapons effects testing for the Defense Threat Reduction Agency (DTRA), managing environmental restoration projects for the Department of Energy (DOE) and private industry, and Facilities and Construction Management work for the DOE and the Air Force. David graduated from the University of New Mexico with a BS degree in Mechanical Engineering and an MS degree in Civil Engineering from New Mexico State University.

David enjoys spending much of his time with his wife Louella, three daughters, and three grandchildren with another one on the way. In his spare time David plays golf and is now looking forward to providing his services to the PCSA.

Continued from page 1

5. **Written Radiology Reports,** if you have received any prostate scans such as CT, Bone, or MRI.

QUESTIONS FOR YOUR UROLOGIST

The items below describe the clinical diagnosis details collected. It is important to understand this is statistical risk derived from analysis of thousands of men. It does not precisely predict for the individual. For example many men with high risk are successfully treated, while some men with low risk may eventually have PSA rising after treatment. It is important to understand we are talking about risk of PSA rising, not risk of imminent prostate cancer death. There are many effective treatments for rising PSA.

1. PSA at Diagnosis (just before positive biopsy): PSA 0 to 6 is very low risk, 6-10 low-risk, 10-20 intermediate-risk, >20 high-risk, and >100 is advanced disease.

2. Clinical Stage: Determined by the digital rectal exam (DRE):

T1c = no tumor felt with the finger (lowest risk)
T2a = small nodule on one side (low-risk)
T2b = larger nodule in more than half of one side (intermediate-risk)
T2c = nodules on both sides of prostate (intermediate/higher risk)
T3 = cancer detected outside of prostate but not invading local tissue (high-risk)
T4 = cancer invades local tissue such as bladder or rectum (high-risk)

3. Prostate Size (volume), in grams or cc: When the urologist performs a prostate biopsy, he or she uses an ultrasound machine to scan the prostate and aim the biopsy needles. At that time, they usually will also calculate the size of the prostate. Size can vary greatly, from less than 25 cc to more than 100 cc. Over 60 cc is enlarged enough to require special consideration when evaluating the radiation therapy options.

4. The PSA Density calculation (PSA ÷ prostate volume) takes prostate size into account. Enlarged prostates produce more PSA (even without cancer), and this higher PSA should be considered when evaluating risk. For example, a PSA of 10 places a man at intermediate-risk. But if the prostate size was 100 cc, most of that PSA may be coming from the large prostate, indicating that the man actually has a low-risk PSA. His PSA density would be normal at 10/100 = 0.10. A PSA Density greater than 0.15 raises concern, because the PSA is high relative to the size of the prostate, and may indicate more extensive disease somewhere.

5. Age at Diagnosis: Take age (and overall health) into account when choosing a treatment option. Perhaps a man who is older or in ill health will choose less intense therapy in place of radical therapy and its side effects.

6. Highest Gleason Score Sum: The pathologist will assign a Primary Gleason Grade to the larger percentage involved, and a Secondary Gleason Grade to the lesser percentage involved in each biopsy core. The Gleason Score is the sum of Primary Grade + Secondary Grade (for example, 4+3=7). Use the core with the highest score. Gleason Grade 3 is the lowest grade normally reported as cancer, and is the lowest risk. When the cells look more different than healthy cells (poorly differentiated), they are assigned a higher Gleason Grade of 4 or 5. Grade 4 and 5 cancer cells are more dangerous because they tend to invade local tissue or spread to the lymph nodes or bones. Greater amounts of grade 4 or 5 cancer in the prostate is associated with higher risk. For determining overall risk, the core with the highest Gleason score is used as the risk reference.

Gleason 3+3=6 lowest risk **Gleason 3+4=7 low-intermediate risk**
Gleason 4+3=7 high-intermediate risk **Gleason Score 8, 9, 10 high risk**

7. Number of biopsy cores taken

8. Number of biopsy cores positive: The more cores with cancer, the higher the risk that cancer might already be outside the prostate.

9. Percentage of Cores Positive = (number positive / total cores): More than 1/3 of cores positive raises the risk of cancer already outside the prostate. Over half of cores positive is high-risk.

10. Greatest core percentage of cancer found in the most involved core: If a core is more than 50% involved, there is more risk the cancer may be outside the prostate at that location.

11. Is there MRI , CT scan, or DRE evidence of Extra Prostatic Extension (ECE or EPE)? Cancer outside the prostate locally (stage T3) might still be eradicated, but more aggressive therapy may be required.

12. Any positive lymph nodes, within the pelvis, identified with MRI or CT Scan? Local therapy to only the prostate may not be enough. Research whether External Beam Radiation Therapy (EBRT) around the prostate and/or systemic therapy will be beneficial. (Stage N1, high-risk)

13. Bone metastases confirmed by a positive bone scan is Stage M1, advanced disease.

14. Any positive node beyond the pelvis? A metastasis in soft tissue outside the pelvis is high risk.

15. Comorbidities and other health problems, such as heart disease, diabetes or urinary retention, should be taken into account before initiating aggressive therapy. Perhaps the side effects of cancer treatment should be avoided, or less toxic therapies can be tried.

PCRI Helpline educational facilitators are specially trained to assist with understanding these medical records, and can be reached at 1-800-641-7274, or help@pcri.org if you need assistance., OR PCSANM support facilitators.

D*ISCLAIMER – This article is intended to assist the prostate cancer patient to understand their disease diagnosis, and to outline questions to discuss with their doctor. It should never be considered actual medical advice.*

What's new in prostate cancer research and treatment?

From American Cancer Society website www.cancer.org

Research into the causes, prevention, and treatment of prostate is going on in many medical centers throughout the world. Additional details on the following information may be found on the following link: http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-new-research

Prevention

Researchers continue to look for foods (or substances in them) that can help lower prostate cancer risk. Scientists have found some substances in tomatoes (lycopenes) and soybeans (isoflavones) that might help prevent prostate cancer. Studies are now looking at the possible effects of these compounds more closely. Scientists are also trying to develop related compounds that are even more potent and might be used as dietary supplements. So far, most research suggests that a balanced diet including these foods as well as other fruits and vegetables is of greater benefit than taking these substances as dietary supplements.

Staging

Staging plays a key role in deciding which treatment options a man may be eligible for. But imaging tests for prostate cancer such as CT and MRI scans can't detect all cancers, especially small areas of cancer in lymph nodes.

A newer method, called *enhanced MRI*, may help find lymph nodes that contain cancer. Patients first have a standard MRI. They are then injected with tiny magnetic particles and have another scan done the next day. Differences between the 2 scans point to possible cancer cells in the lymph nodes. Early results of this technique are promising, but it needs more research before it becomes widely used.

A newer type of positron-emission tomography PET scan that uses radioactive carbon acetate instead of FDG may also be helpful in detecting prostate cancer in different parts of the body, as well as helping to determine if treatment has been effective. Studies of this technique are now in progress.

Treatment

This is a very active area of research. Newer treatments are being developed, and improvements are being made among many standard prostate cancer treatment methods.

Surgery

If the nerves that control erections (which run along either side of the prostate) must be removed during the operation, a man will become impotent. Some doctors are now exploring the use of nerve grafts to replace cut nerves and restore potency. These grafts could be nerves removed from other parts of the body or something artificial. This is still considered an experimental technique, and not all doctors agree as to its usefulness. Further study is under way.

Radiation therapy

Advances in technology are making it possible to aim radiation more precisely than in the past. Currently used methods such as conformal radiation therapy (CRT), intensity modulated radiation therapy (IMRT), and proton beam radiation allow doctors to treat only the prostate gland and avoid radiation to normal tissues as much as possible. These methods are expected to increase the effectiveness of radiation therapy while reducing the side effects. Studies are being done to find out which radiation techniques are best suited for specific groups of patients with prostate cancer.

Technology is making other forms of radiation therapy more effective as well. New computer programs allow doctors to better plan the radiation doses and approaches for both external radiation therapy and brachytherapy. Planning for brachytherapy can now even be done during the procedure (intraoperatively).

Nutrition and lifestyle changes

One early study has found that in men with a rising PSA level after surgery or radiation therapy, drinking pomegranate juice seemed to slow the time it took the PSA level to double. Larger studies are now trying to confirm these results.

Some encouraging early results have also been reported with flaxseed supplements. One small study in men with early prostate cancer found that daily flaxseed seemed to slow the rate at which prostate cancer cells multiplied. More research is needed to confirm this finding.

Another study found that men who chose not to have treatment for their localized prostate cancer may be able to slow its growth with intensive lifestyle changes. The men ate a vegan diet (no meat, fish, eggs, or dairy products) and exercised frequently. They also took part in support groups and yoga. After one year the men saw, on average, a slight drop in their PSA level. It isn't known if this effect will last since the report only followed the men for 1 year. The regimen may also be hard to follow for some men.

Hormone therapy
Several newer forms of hormone therapy have been developed in recent years. Some of these may be helpful even if standard forms of hormone therapy are no longer working.
An example is abiraterone (Zytiga®), a drug that blocks an enzyme called *CYP17*. This drug was recently approved to help treat advanced prostate cancer.
Abiraterone is used mainly in men with advanced prostate cancer that is still growing despite low testosterone levels (from LHRH agonists or orchiectomy), and who have already been treated with the chemotherapy drug docetaxel (Taxotere®). Abiraterone has been shown to shrink tumors, lower PSA levels, and help these men live longer.
Doctors are now looking to see if this drug might be helpful earlier in the course of the disease as well. This drug is taken as a pill every day. Because abiraterone lowers the level of certain other hormones in the body, prednisone (a cortisone-like drug) needs to be taken as well during treatment.
Another new drug that works in a similar way, known as *orteronel*, is now being studied. This drug may target CYP17 more precisely, which may do away with the need for taking a steroid drug such as prednisone along with treatment. Orteronel is only available in clinical trials at this time.
MDV3100 is a newer type of anti-androgen that binds to the androgen receptor more strongly than standard anti-androgen drugs. This may make it more effective, even after other types of hormone therapy have been tried. This drug is now in late-phase clinical trials.

Chemotherapy
Studies in recent years have shown that many chemotherapy drugs can affect prostate cancer. Some, such as docetaxel (Taxotere) and cabazitaxel (Jevtana) have been shown to help men live longer. Other new chemo drugs and combinations of drugs are now being studied.

Prostate cancer vaccines
Several types of vaccines for boosting the body's immune response to prostate cancer cells are being tested in clinical trials. Unlike vaccines against infections like measles or mumps, these vaccines are designed to help treat, not prevent, prostate cancer. One possible advantage of these types of treatments is that they seem to have very limited side effects. An example of this type of vaccine is sipuleucel-T (Provenge), which has received FDA approval.
Another prostate cancer vaccine (PROSTVAC-VF) uses a virus that has been genetically modified to contain prostate-specific antigen (PSA). The patient's immune system should respond to the virus and begin to recognize and destroy cancer cells containing PSA. Early results with this vaccine have been promising.
Several other prostate cancer vaccines are also in development.

Angiogenesis inhibitors
Growth of prostate cancer tumors depends on growth of new blood vessels (angiogenesis) to nourish the cancer cells. Looking at angiogenesis in prostate cancer specimens may help predict treatment outcomes. Cancers that stimulate many new vessels to grow are harder to treat and have a poorer outlook.
New drugs are being studied that may be useful in stopping prostate cancer growth by keeping new blood vessels from forming. Several anti-angiogenic drugs are being tested in clinical trials. One of these is thalidomide (Thalomid®), which has been approved by the FDA to treat patients with multiple myeloma. It is being combined with chemotherapy in clinical trials to treat men with advanced prostate cancer. While promising, this drug can cause major side effects, including constipation, drowsiness, and nerve damage.
Another drug, bevacizumab (Avastin®), is FDA-approved to treat patients with other cancers. It is now being tested in combination with hormone therapy and chemotherapy in men with advanced prostate cancer.

Preventing or treating spread of cancer to the bones
Several newer medicines may help prevent or treat prostate cancer spread to the bones.
Radium-223 (Apharadin) is a radioactive medicine given as an injection into a vein. It travels throughout the body, bringing small doses of radiation to prostate cancer cells in the bones. In a large study of men with prostate cancer that had spread to bone but was no longer helped by hormones, this drug helped men live an average of a few months longer. It is now being reviewed for approval by the FDA.
Cabozantinib (XL184) is a new drug that targets the MET protein, as well as having an effect on angiogenesis by targeting the VEGFR protein. In an early study, this drug was found to make bone tumors get smaller or even go away on imaging scans in many men with prostate cancer that was no longer responding to hormones. This was a very promising and unusual early finding, although it's not clear how long this might last or if the drug can help men live longer. Larger studies are now under way to try to answer these questions.
Doctors are also studying the use of radiofrequency ablation (RFA) to help control pain in men whose prostate cancer has spread to one or more areas in the bones. During RFA, the doctor uses a CT scan or ultrasound to guide a small metal probe into the area of the tumor. A high frequency current passed through the probe heats and destroys the tumor. RFA has been used for many years to treat tumors in other organs such as the liver, but its use in treating bone pain is still fairly new. Still, early results are promising.

Perspectives on Prostate Cancer Screening

Richard M. Hoffman, MD, MPH

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A New England Journal of Medicine editorialist referred to prostate cancer screening as the controversy that refuses to die. In the past year, prostate cancer screening has captured much public attention. Two major screening trials both published updated results. After 9 years of follow-up, the American Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial remained a negative study, with no evidence that screening reduced the chance of dying from prostate cancer. However, the PLCO results have been challenged because a high proportion of men in the control group received PSA tests. Although designed to compare screening with no screening, PLCO ended up comparing frequent screening with less frequent screening. Furthermore, only a minority of men with abnormal PSA tests actually underwent a biopsy. Both of these factors could contribute to the negative findings.

In contrast, the European Randomized Study of Prostate Cancer Screening (ERSPC) continued to show a survival benefit for screening. Compared to PLCO, more men in the ERSPC trial with abnormal PSA levels underwent biopsy and fewer men in the control group had PSA testing. Overall, men in the screening group were 20% less likely to die from prostate cancer. The absolute benefit was small--about 1 in 1000 after 11 years of follow up. However, this was a larger benefit than was reported in an earlier publication. That screening appears more effective over time is not surprising. Because PSA can detect a cancer 5 to 10 years before it can be felt on digital rectal exam, screening trials potentially need decades of follow up to estimate the true benefit of screening. Indeed, a modeling study recently published in the New England Journal estimated that the benefit of screening could be substantially greater after 20 years of follow up. However, accurately estimating the long-term benefit is difficult because men in both screened and unscreened groups are increasingly at risk for dying from other causes.

Both screening studies showed that PSA testing was associated with a markedly increased risk for diagnosing prostate cancer. Researchers are concerned that many of the cancers found by PSA are overdiagnosed—microscopic cancers that would never have caused symptoms during a man's lifetime. Because most men with cancer attempt curative therapy with surgery or radiation, experts argue that men with overdiagnosed cancers unnecessarily face the harms of treatment.

Recently published results from the Prostate Cancer Intervention Versus Observation Trial (PIVOT) add further support for this concern. The PIVOT randomly assigned men with localized prostate cancer, the majority of whom had been detected by PSA screening, to either radical prostatectomy or watchful waiting. After a median 10 years of follow up, men who underwent radical prostatectomy were not significantly less likely than men in the watchful waiting group to have died from prostate cancer. However, subgroup analyses suggested potential survival and metastasis benefits for radical prostatectomy among men with high-risk tumor characteristics (based on tumor stage, Gleason, and PSA). Men with low-risk tumor characteristics had essentially the same risk of prostate cancer death whether they underwent surgery or watchful waiting.

Of course, the most inflammatory news stories have centered on screening guidelines. The recent United States Preventive Services Task Force (USPSTF) "D" recommendation against performing any PSA testing, regardless of age or risk factors, has been a bombshell in the world of prostate cancer screening. The American Urological Association (AUA) and advocacy groups have repeatedly attacked the guideline, alerting the public, media, and lawmakers concerning the potential harms of this recommendation.

Additionally, several authors of the American Cancer Society (ACS) screening guideline also challenged the Task Force, particularly the conclusion that the evidence showed no benefit. The ACS authors argued that two studies did show a small cancer survival benefit and that prostate cancer screening warrants a "C" recommendation, indicating that "[there may be considerations that support providing the service in an individual patient." A "C" recommendation would promote individualized decision-making.

Clearly, after 20 years of aggressive screening, health care providers and American men will not go quietly into an era of no screening. Screening will still be requested and offered. Providers have an obligation—as noted even by the USPSTF—to ensure that men make informed decisions. This requires educating men about the potential lifetime harms and benefits of screening—a daunting task given that randomized trials had relatively short-term follow-up and inconsistent results and because recent guidelines advocate screening strategies that were not evaluated in the trials. Unfortunately, these discussions often do not take place and when they do men often receive unbalanced (usually favorable) perspectives on screening.

One effective strategy for supporting decision-making is to provide men with a decision aid. Decision aids are evidence-based tools that help patients make decisions when there is no clear-cut best option. A decision aid, which can be written, audio, video, or web-based, can provide patients with detailed and balanced information abut the health condition, the possible options, the associated potential harms and benefits, and the scientific uncertainties. Studies have shown that men who receive a decision aid increase their knowledge, are more likely to participate in the decision-making process, feel more confident in their decisions, and are less likely to want screening. The ACS guidelines strongly encourage providers to use decision aids and provides a list, including one that I edit: https://www.healthcrossroads.com/example/crossroad.aspx?contentGUID=fc326615-5b29-47f1-87c3-9a3e2d946919

Another important point about screening is that the harms from overdiagnosis can be limited by preventing overtreatment. We recognize that cancers with low-risk features are unlikely to ever cause harm. Because none of the currently available prognostic markers are perfectly accurate, men have been concerned about not treating a potentially dangerous cancer and usually opt for active treatment. However, an alternative strategy has been proposed—active surveillance (AS)—that avoids immediate treatment. With AS, men are regularly followed with PSA, digital rectal exam, and prostate biopsies.

Active treatment will be offered if and when the cancer appears to be progressing (or whenever requested). Observational studies suggest that AS is an effective and safe strategy. A substantial number of men do avoid active treatment and reports from major urological centers indicate that none of their patients have died from prostate cancer after initially selecting AS. The National Institutes of Health convened a state-of-the science conference last December to evaluate AS. The summary report concluded that active surveillance is a viable option that should be offered to patients with low-risk prostate cancer, though numerous research questions need to be answered regarding patient selection, patient decision making, AS protocols, and long-term outcomes.

Decisions about undergoing screening and selecting treatment are complex. The best strategy is for a man to be well informed about the options, clear about his values for potential outcomes, and to work with his health care providers to make the decisions that are best for him.

Enzalutamide: Next New Drug for Prostate Cancer?

Zosia Chustecka From: Medscape Medical News

August 15, 2012 —The investigational drug enzalutamide (formerly known as MDV3100, Medivation) looks set to be the next new treatment for prostate cancer.

A pivotal phase 3 trial, known as AFFIRM (A Study Evaluating the Efficacy of the Investigational Drug MDV3100), showed a survival advantage and therefore was stopped early. Results were published online August 15 in the *New England Journal of Medicine*.

The manufacturer announced recently that its approval application was accepted by the US Food and Drug Administration; the agency granted it a Priority Review designation, and a decision is expected by November 22. The drug is also under review in Europe.

The approval covers the use of enzalutamide in the treatment of castration-resistant prostate cancer (CRPC) in men previously treated with docetaxel-based chemotherapy.

This is the indication explored in AFFIRM. The study of 1199 patients showed that enzalutamide significantly prolonged median overall survival, compared with placebo (18.4 vs 13.6 months; hazard ratio, 0.63; $P < .0001$).

This difference became apparent after a planned interim analysis, and led to the trial being halted early (in November 2011) so that the men taking placebo could cross over to the active drug.

The AFFIRM results were presented earlier this year at the Genitourinary Cancers Symposium, as reported by *Medscape Medical News*, when Nicholas Vogelzang, MD, from US Oncology Research, said: "Wow! Very Impressive!" The 18.4-month median survival seen with enzalutamide is "unprecedented," he noted during a meeting presscast that he moderated.

AFFIRM coauthor Howard Scher, MD, chief of the genitourinary oncology service at Memorial Sloan-Kettering Cancer Center, New York City, said that "the results of the trial have exceeded our expectations."

The product was coinvented by Charles Sawyers, MD, also from Sloan-Kettering, and Michael Jung, PhD, professor of chemistry at the University of California, Los Angeles. They had observed that men with CRPC often build up resistance to hormone therapy because the tumor increases its production of androgen receptors. Therefore, they designed the drug to specifically target and bind to androgen receptors in tumor cells.

Enzalutamide acts as a very potent antagonist of androgen receptors, and binds to the receptors very tightly, Dr. Scher previously told *Medscape Medical News*. This makes it both more potent and more specific than older antiandrogens, some of which have both agonist and antagonist activity, he explained. It also led to the "super antiandrogen" nickname.

"Prostate cancers that progress after standard hormones and chemotherapy are notoriously difficult to treat," Dr. Scher said in a statement.

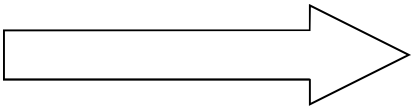
"It is extremely gratifying to see how the close integration of clinical observations and fundamental laboratory discoveries have come together to provide a new and effective potential treatment that can prolong the lives of men with this disease," he added.

Enzalutamide article Continued:

"These results validate androgen-receptor signaling as a key therapeutic target throughout the clinical spectrum of prostate cancer, including in men who have received previous chemotherapy," the study authors write.

Dr. Frederick Snoy has talked to us at Support Group meeting about his research studies. He has ongoing studies for BPH, and prostate cancer.

He is working on setting up a database of men with prostate/urology problems, so that when he starts a new study, he will have some names on file. You can fill out the attached form, and mail it or take it to his office.



Enzalutamide article continued

Where Will it Fit?

The prostate cancer market has exploded in the past couple of years. Three new drugs for use in the CRPC patient population have recently been launched: cabazitaxel (Jevtana, sanofi-aventis), a new chemotherapy; sipuleucel-T (Provenge, Dendreon), an immunotherapeutic vaccine; and abiraterone (Zytiga, Johnson & Johnson), an androgen-synthesis inhibitor.

All of these products have been shown to improve survival in CRPC, but there are no clear guidelines — yet — on which product should be used when.

There is, however, plenty of discussion on this topic. Pharmaceutical business analysts have tipped abiraterone and enzalutamide as having blockbuster potential (with sales of more than $1 billion) and expect these 2 drugs to compete closely with one another. Both target androgen, but by different mechanisms. Another difference is that abiraterone needs to be used in combination with prednisolone, whereas enzalutamide does not.

There is also interest in seeing how enzalutamide and abiraterone, with their different approaches to androgen inhibition, will fare when they are used in combination with one another.

Dr. Garnick, who was not involved in the enzalutamide trial, told Medscape Medical News that "the sequencing of drug choices in the CRPC patient population is now challenging."

"But it's a nice challenge to have, since options now exist that did not in the past," he added.

"The exciting aspect of having another agent that effects meaningful anticancer responses, with a defined mechanism of action and acceptable safety features, will greatly enhance the design of future studies that will hopefully provide even greater improvements," Dr. Garnick noted.

Patient Information for Prostate Cancer Research Studies

If you would like to be contacted about Prostate Cancer Clinical Research Study Opportunities – Please fill out this form and send it to Dr. Frederick Snoy, Urology Group of New Mexico-Clinical Research; 4161 Montgomery Blvd. NE, Albuquerque, NM 87109. We will keep your information confidential in accordance with HIPPA standards and contact you if you appear to be eligible for any active or upcoming Prostate Cancer Clinical Studies

Name:_____

Address:_____

City:_____ State:_____

Zip:_____

Phone:_____

E-mail:_____

Gleason Score:_____

Date of Diagnosis :_____(approximation is ok)

PSA at time of Diagnosis:_____

Treatments and dates received:

_____

_____

(surgery, radiation, Lupron, other)

Current PSA:_____

I give permission for Dr. Snoy and or Urology Group Research to contact me about possible prostate cancer related clinical research studies.

Signed_____ **Date:**_____

PCSA *Lifeline* Newsletter
October 2012

Prostate Cancer Support Association
of New Mexico, Inc.
909 Virginia NE, Suite #109
Albuquerque, NM 87108

Chairman's Corner

I am pleased to have been elected by your Board of Directors for the position of Chairman. This is a great responsibility and I look forward to steering this organization into the future. But first, I have to give a big thanks to our former Chairman, Bob Wood. He did a good job guiding us for the past 7 years, and especially through the current tough financial times. I hope to do as good a job as he did.

My Vision for PCSANM is much the same as I believe our founder had: A comprehensive organization for educating and communicating Prostate Cancer information to the newly diagnosed, to our Members, and the public throughout Albuquerque and the state of New Mexico. We will continue to conduct one-on-one counseling for the newly diagnosed and share our personal experiences with this disease. I will need the help of all our members to accomplish this vision – I ask that members volunteer their time and energy to help with putting on our activities: meetings; outreach to organizations such as men's groups, churches, senior centers, Pueblos, Indian Reservations, and health fairs; and with maintaining our office and manning the phones.

With your help, I hope our group will continue to be **the place** for Prostate Cancer patients go to for good advice and help in their battle with this disease.

I wish you all good health,

Lou Reimer Chairman of the Board, PCSANM