patients and world-renowned prostate cancer doctors, presenting a wealth of information about treatment options and cutting-edge research...

The PCRI Conference - September 6-8, 2013
Come meet Ryan O’Neal
Lunch with Ryan O’Neal and Duke Bahn, MD
By Mark Scholz, MD

Last month Dr. Duke Bahn invited me to meet him for lunch on the Malibu coast to interview Ryan O’Neal (Love Story, Paper Moon) and to discuss, of all things, focal cryotherapy. It was a beautiful summer day to be at an enjoyable restaurant off the Coast Highway overlooking the ocean. Mr. O’Neal underwent treatment for prostate cancer last year. His treatment turned out favorably so he generously offered to tell his story.

My social life is normally limited to everyday folks so I was naturally curious about meeting Mr. O’Neal. When I arrived at the restaurant, he was already seated in the waiting area. He sprang to his feet offering a warm smile and handshake. We made our way to the table where Dr. Bahn and Ryan’s friend, Greg Hodal, joined us.

Since this is my first celebrity interview, I started timidly, “What’s your daily life like?” Ryan responded, “Well, I live right down the road. Enjoy paddle tennis. Still do some acting. I play the part of the father of Dr. Brennan in the TV show Bones. I’m committed to exercise. Try to ride my stationary bike every day. Actually, I own Pro Gym in Brentwood. Make it over there to work out a couple times a week.”

Ryan was diagnosed with stage T2b (medium sized nodule) and Gleason Grade 7 (intermediate grade) prostate cancer in 2012 when his doctor felt an abnormality on digital rectal examination. “My oncologist, Dr. Piro, was very reassuring and calmed me down. He referred me to Dr. Bahn in Ventura for a prostate scan. The scan showed a distinct nodule contained within the gland (see figure 1). After my scan, I sat down in Dr. Bahn’s office and we reviewed a whole list of treatment options including surgery, beam radiation, radioactive seeds and targeted cryotherapy. I was particularly attracted to the cryotherapy option because of the reduced risk of side effects.”

I asked Dr. Bahn, “What kind of side effects have you been seeing in your patients treated with focal cryotherapy?” He replied, “In the first 100 men, there has been zero incontinence and about ten percent impotence.”

Then, returning to Ryan, I asked, “Were there any other bad effects?” He smiled and said, “I was sore between my legs for a day. I had a catheter for a week so attending a party wasn’t so fun. Got my attention when the urologist pulled it out, but overall I did great. I never needed any pain-killers. I haven’t had any residual effects.”

Mr. O’Neal related that he had faced the diagnosis of serious cancer before. When he was sixty, twelve years ago, he was diagnosed with Chronic Myelogenous Leukemia (CML). “Back then they just came out with a new miracle pill called Gleevec. It put me in complete remission. I faithfully take the pill to this day.”

Ryan was very curious about the controversy surrounding PSA screening and posed a number of insightful questions. Before the meeting I was expecting a jaded Hollywood road warrior. As it turns out, Ryan is extremely personable, a delightfully engaging conversationalist. He was very attentive, asking incisive questions of Dr. Bahn and me about the PCRI and the prostate cancer world in general. While Ryan ate Ahi tuna and I nibbled on Chilean sea bass we covered a wide variety of important themes including the overtreatment of innocuous prostate cancer, the five shades of prostate cancer and the modern potential for reducing side effects using focal therapy, now that scanning technology has been improved.

I asked Ryan how he could afford time away from his busy lifestyle to address a mundane subject like prostate cancer. “I feel very fortunate that my treatment has turned out so well. This is actually my third go round with cancer. I had Moh’s treatment to remove skin cancer. All along I have been privileged with skilled doctors using innovative medical technology. If there is anything I can do to help increase awareness, I need to do it.”

At that point both Dr. Bahn and I interrupted him at the same time. “Well... there is this prostate cancer conference coming up this September. Any chance you could come?” Ryan smiled, “Sure, I’d be happy to come and share. Maybe we can get the LA Times to come and do a story.”

Driving back on the Coast Highway from Malibu to my office in Marina del Rey I was reflecting on Ryan’s playful charm and how he kept steering the conversation back toward Dr. Bahn’s and my comfort zone, the topic of prostate cancer. We all had a great time. No wonder people’s ears perk up when they hear the name—Ryan O’Neal.

Mr. O’Neal’s Cancer on Color Doppler Ultrasound:

Image A: Vascular (red) Prostate Cancer seen at Yellow Arrow

Image B: Cryoaablation: Dark area is Ice Formation to kill the cancer at Arrow

Image C: 14 months after Cryo: The right lobe is deformed and shrunken (Arrow). The cancer has disappeared. No blood flow (red) is detected. PSA 0.7
New Studies Presented at the ASCO and AUA Annual Meetings
By Mark Scholz, MD

Scientific meetings are built around the presentation of results from new studies. For example, in the last issue of PCRI Insights I summarized the findings from several new studies presented at the February Genitourinary meeting of the American Society of Clinical Oncology (ASCO). Since that time, in May and June, two even larger medical meetings have occurred: the annual meeting of the American Urological Association, the AUA, and another, larger ASCO meeting. I have selected some reports from these two meetings and comment on them in this article.

**Abstract 5001**

Dr. Smith and colleagues administered Xtandi 160 mg daily for 25 weeks to 67 men who had no previous TIP. The side effects reported were breast enlargement and fatigue in about a third of the men and hot flashes in one-fifth. Effects on libido and potency were not reported. Mean decrease in PSA was 99.6%; testosterone and estrogen levels increased 114% and 72%, respectively. Bone density and fat body mass increased, 5.5 years. Aspirin use was associated with a significant decreased risk of prostate cancer-specific and all-cause mortality in a dose-dependent fashion. The adjusted hazard ratio, for prostate cancer diagnosis, was associated with high-grade tumors and poorer prognosis. Use of aspirin, a COX-2 inhibitor, have been associated with reduced prostate cancer mortality in some studies.

**Abstract 5084, Aspirin**

Cyclooxygenase-2 (COX-2) expression in prostate cancer has been associated with high-grade tumors and poorer prognosis. Use of aspirin, a COX-1 & 2 inhibitor, have been associated with reduced prostate cancer mortality in some studies.

**Abstract 5007, Metformin**

Data were obtained from several Ontario health care administrative databases.

**Results:** The cohort consisted of 3,837 patients. Cumulative duration of metformin treatment, after prostate cancer diagnosis, was associated with a significantly lower risk of prostate cancer-specific and all-cause mortality in a dose-dependent fashion. The adjusted hazard ratio for prostate cancer-specific mortality was 0.76 for each additional six months of metformin use. The association with all-cause mortality was also significant but declined over-time from a HR of 0.76 in the first 6 months to 0.93 between 24-30 months.

**Conclusions:** Increased cumulative duration of metformin exposure after prostate cancer diagnosis was associated with decreases in both all-cause and prostate-cancer-specific mortality among diabetic men.

**Comment:** This report substantiates other previously published studies on the anticaner effects of metformin (otherwise known as Glucophage). Like vegetarian and macrobiotic diets, metformin lowers insulin levels. Insulin, which is like a type of growth hormone, has been implicated as a causative agent that accelerates cancer growth. In my book, Invasion of the Prostate Snatchers, a whole chapter was devoted to the important topic of how insulin affects prostate cancer.

Aspirin, Metformin, Sulforaphane (Broccoli), Polyphenols and Vitamin D for PCa

Prostate cancer tends to be a slow-growing disease. Survival, even after relapse from surgery or radiation, is similar to men who don’t have prostate cancer. Even so, many who relapse require intermittent therapy with TIP to control the disease. After a period of years, some men can become refractory to TIP and some of these who are refractory will have their lives shortened by the disease. Agents that can further impede the already slow growth rates of prostate cancer have the potential to significantly improve survival (for example, if a hypothetical cancer is doubling at a rate of every six months and could be slowed down to a doubling rate of every nine months, life expectancy could be prolonged 50%). A number of supplements have shown cancer inhibitory qualities. Several reports presented at the cancer meeting confirmed their effects on PCa.

**Abstract 5084, Aspirin**

Cyclooxygenase-2 (COX-2) expression in prostate cancer has been associated with high-grade tumors and poorer prognosis. Use of aspirin, a COX-1 & 2 inhibitor, have been associated with reduced prostate cancer mortality in some studies.

**Methods:** National Cancer Registry Ireland data was used to identify men with stage I-III prostate cancer, diagnosed from 2001-2006. Aspirin use in the year preceding prostate cancer diagnosis was identified. Cox proportional hazards models, adjusted for age, smoking status, year of incidence, comorbidity score, Gleason score, tumor size, pre-diagnostic statin use, and receipt of radiation (time varying) were used to estimate hazard ratios (HR) for associations between aspirin use and all-cause and prostate cancer-specific mortality.

**Results:** 2,936 men were identified. Median follow-up was 5.5 years. Aspirin use was associated with a significantly lower risk of prostate cancer-specific mortality in men receiving >75mg of aspirin. Stronger associations were observed in men with higher aspirin dosing or a Gleason score >7.

**Conclusions:** Pre-diagnostic aspirin use was associated with a significant reduction in prostate cancer-specific mortality in men receiving >75mg of aspirin.

**Comment:** We know that aspirin 81 mg daily cuts the risk of coronary events in men by one-third. Typically, side effects, mainly gastric upset or ulcers are rare. One of the good things about aspirin is that it is a blood thinner. Other blood thinners (such as Gomadin) have been shown to prolong prostate cancer survival (see the article I wrote in the last issue of Insights). This new report on aspirin supplies further evidence that daily aspirin should be considered routine in men with prostate cancer.

Xtandi for Hormone Sensitive Disease and as a Primary Treatment Option for PCa

Over the years at Prostate Oncology Specialists where I work, we have championed the use of testosterone inactivating pharmaceuticals (TIP)—also known as hormone therapy or ADT—as a primary treatment alternative to surgery or radiation. Ten years ago, when severe radiation side effects were common, TIP was preferable to radiation because TIP had fewer side effects. However, as radiation technology has improved, we have been relying less and less on TIP.

However, Xtandi, a potent new type of TIP, may cause us to consider hormone therapy as an equally viable and effective primary treatment option. Even though Xtandi was FDA approved for treating advanced hormone-refractory prostate cancer, there is reason to believe it can be effective in the earlier stages of the disease. It’s quite conceivable that Xtandi will be a more effectual treatment than the traditional LHRH agonists such as Lupron, Trelstar, Eligard and Zoladex, while causing less post-treatment side effects.

**Comment:** Xtandi seems like the logical choice for men interested in TIP as a primary form of therapy because it “blocks” testosterone activity rather than completely shutting it down (as do the LHRH agonists). As such, the recovery period when the treatment is over should be much shorter. At Prostate Oncology Specialists we are presently investigating the use of six months of Xtandi with Femara (to prevent breast growth) in men with Intermediate-Risk Disease.

**Abstract 5001**

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Aspirin, Metformin, Sulforaphane (Broccoli), Polyphenols and Vitamin D for PCa

Prostate cancer tends to be a slow-growing disease. Survival, even after relapse from surgery or radiation, is similar to men who don’t have prostate cancer. Even so, many who relapse require intermittent therapy with TIP to control the disease. After a period of years, some men can become refractory to TIP and some of these who are refractory will have their lives shortened by the disease. Agents that can further impede
Abstract 5017--Sulforaphane
Patients with PSA recurrence were treated with 200 μmol of sulforaphane extract for up to 20 weeks.

♦ Results: Sixteen patients completed 20 weeks of treatment. One patient experienced a PSA decline >50%. Thirty-five percent of patients had lesser PSA declines (3% to 20%), and 15% of patients had a final PSA lower than baseline. There was a significant reduction in PSA doubling time (6 months pre-study vs. 9.4 months on-study, p=.013). One patient discontinued study treatment for grade one GI discomfort.  

♦ Conclusions: This study provides a preliminary observation of improved PSA modulation with sulforaphane in men with prostate cancer.  

♦ Comment: Sulforaphane is thought to be the active ingredient in broccoli. Sulforaphane increases the intracellular concentration of an important anti-oxidant enzyme called glutathione transferase, which is abnormally suppressed in prostate cancer cells. This small study provides further evidence for the possible anticancer effects of sulforaphane.

Abstract 5036, Vitamin D
Emerging evidence in the literature suggests a positive association between serum 25-hydroxyvitamin D and survival in certain types of cancer.

♦ Methods: A case series of 54 newly diagnosed stage IV prostate cancer patients underwent vitamin D evaluation prior to receiving treatment. We defined vitamin D insufficiency as serum 25(OH)D levels of <=32 ng/ml. Cox regression was used to evaluate the prognostic significance of vitamin D on survival after adjusting for age, PSA and functional status.

♦ Results: Mean survival was 32.6 months and 62.4 months for patients in <=32 ng/ml and >32 ng/ml groups respectively (p = 0.02). On multivariate analysis controlling for age, performance status and PSA, patients with levels >32 ng/ml demonstrated significantly lower mortality (HR=0.13; p=0.05) compared to those with levels <=32 ng/ml.

♦ Conclusions: Higher circulating levels of Vitamin D were positively associated with survival in patients with metastatic prostate cancer.

Abstract 5008, Polyphenol-rich food
Foods such as pomegranate, green tea, broccoli and turmeric have anti-neoplastic effects in cell lines and animal models.

♦ Methods: 203 men with localized prostate cancer after PSA relapse were randomized to receive an oral capsule containing a blend of pomegranate seed, green tea, broccoli and turmeric or placebo for 6 months.

♦ Results: The median rise in PSA was 14.7% versus 78.5% with Placebo, p=0.0008. 46% of men had stable or lower PSA at trial completion versus 14% in the men treated with placebo. Mild gastro-intestinal issues were the only side effects.

♦ Conclusions: This study found a short-term favorable effect on the percentage rise in PSA.

♦ Comment: All these substances: pomegranate, green tea, broccoli and turmeric (curcumin) have been previously implicated as having inhibitory effects on cancer growth. In this study all four substances combined had a fairly dramatic effect on PSA progression.

Abstract 5022, Mortality from Biopsy
Among 12,300 prostate biopsies, 36 deaths occurred within 120 days; Thirty-two deaths out of 9,124 (0.35%) occurred in the positive biopsy group compared to 4 out of 3,176 (0.13%) in the negative biopsy group. In this latest group, this represents 1.3 deaths per 1,000 biopsies.  

♦ Conclusions: The mortality rate at 120 days following prostate biopsy of 1.3 deaths per 1,000 biopsies, in a population free of cancer, is a serious concern for the computation of benefit risk associated with PSA testing. This figure is in line with the risk reported by Gallina et al (2008) and is now based on a properly monitored population. This prostate biopsy mortality would occur earlier than any benefit from a screening program and could reverse any potential gain from screening such as recorded in ERSPC study.

♦ Comment: PSA screening followed by random biopsy was shown to reduce all-cause mortality in a 180,000 man study done in Europe. However, the US Preventative Services Task Force has cautioned that the negative effect of unnecessary treatment in men with low-grade prostate cancer outweighs the survival benefits. Studies like this one show there is a small but real risk of death from prostate biopsy. This is a strong indication that some form of imaging such as multiparametric MRI or Color Doppler ultrasound should be performed rather than jumping immediately to a random needle biopsy.

Final Thoughts
Although no groundbreaking treatments were presented at this year's urology and oncology meetings, some thought provoking study results were presented. Xtandi shows important advancements that could potentially revolutionize hormone treatment, providing an attractive alternative for men with intermediate stage prostate cancer. Reports are providing strong evidence that supplements and pharmaceuticals like Aspirin, Metformin, Sulforaphane, Polyphenols and Vitamin D have genuine, visible anti-cancer effects. Lastly, a rigorous study further confirms that subjecting men to prostate biopsies can be unnecessarily dangerous, even fatal. Hopefully, prostate imaging rather than biopsy will become the first course of action for evaluating men with high PSA levels.
New Biomarker Tests for Prostate Cancer
By Dean James Foster, MD

Biomarker Tests Guide PCa Treatment
A bio-revolution is taking shape in the rational treatment of prostate cancer. It is being led by the rapid development of biomarker tests for prostate cancer.

This article will cover paraffin fixed tissue biomarker tests. Other tests of blood and urine are also being developed and will be covered in the future. These tests can accurately inform men with indolent prostate cancer that they can safely enter active surveillance, keeping them from the harm of over-treatment. In addition, biomarker tests are helping determine when there is aggressive disease that does need treatment.

Molecular Profiling
These biomarkers are detected molecular signatures, profiling the cell’s metabolic processes. They change when progressive mutations sequentially derange normal processes and lead to cancer. These sequential changes in the cancer cell can now be detected in the blood, urine, semen, and from within the cancer biopsy or surgery tissue itself. By molecularly profiling these changes with the clinical behavior of the tumor, these tests improve accuracy of PCA detection and prediction of treatment outcome. These tests require tissue, so check beforehand how much is required. Also, more recent biopsies are preferred, so check about time limits for specimens.

Proving the Value of New Biomarkers
As promising as all this sounds, new biomarker tests are just getting off the ground. They will need time/ testing to work out the bugs. This happened with the PSA. A widely used biomarker, the PSA has taught us valuable lessons about the pros and cons of biomarkers in general. For example, one drawback of PSA screening is that it has led to overtreatment of low risk disease. In fact, this is one of the motivations for the biotech industry to develop more sensitive and specific biomarker tests.

Tests That Improve the Accuracy of a Negative Biopsy

Prostate Cancer Mitomic Test (PCMT)
A recent publication from the Sunnybrook Division of Urology has found that the PCMT test can accurately predict when a biopsy is truly negative or if it missed the tumor (1,2). Mitomics predicts if tumor is present or around the tumor by detecting mitochondrial DNA deletions commonly found in the tumor

Pros: Very sensitive in detecting prostate cancer and if both the biopsy and PCMT are negative it predicts that there is no need for a second biopsy with 91% accuracy.

Cons: If it detects a nearby tumor, it cannot determine its aggressiveness and does not help predict risk. It therefore requires the need for a repeat biopsy.

The test is available now through QDX Pathology Services as the “QPredict PCMT”. It must be ordered by your physician by calling (866) 909-7204 or online at http://www.qdxpath.com/QPredict legality pdf.

Confirm MDX Test
In two recently published studies, researchers in Johns Hopkins Brady Urologic Institute and U. of Edinburgh Urological Cancer Group confirm that epigenetic changes (cellular changes other than DNA mutation) can accurately predict if the biopsy needle missed cancer. These studies found that the levels of GSTP1, APC and RASSF1 in “normal” surrounding the cancer can determine if there truly is no cancer nearby with a 90% predictive value (3,4). This test helps men avoid a repeat biopsy (with the 1 in 1000 + risk of infection and even death) and confirms the absence of cancer in the prostate.

Pros: This test on biopsy tissue is designed to help men with a negative biopsy avoid a repeat biopsy by confirming the absence of PCs with 90% accuracy.

Cons: It does detect a nearby tumor, it does not determine its aggressiveness or predict risk. It therefore requires the need for a repeat biopsy.

The test is restricted to tissue submitted within 24 months of biopsy. It is available now and is physician ordered by phone (866) 259 5644 and online at http://www.mdxhealth.com. Costs start at ~ $2,000.

Tests That Improve the Accuracy of Pathologic Grading of a Positive Biopsy or Radical Prostatectomy Specimen

OnctypeDX Test (Genomic Prostate Score)
Researchers analyzed RNA from 17 genes across multiple biological pathways (3 stromal response, 4 cellular organization, 3 androgen, 1 proliferation, and 5 reference genes) in radical prostatectomy and prostate biopsy specimens and found a gene signature that helps predict prostate cancer aggressiveness. To simplify reporting, the test result is rendered as a number: the Genomic Prostate Score. It ranges from between 0 (low) to 100 (high). The number is then added to the CAPRA Score (CAPRA-S for RP specimens), significantly improving the Score's predictive accuracy.

In a UCSF study of 395 prostatectomy and biopsy specimens, the genetic patterns reclassified low risk men into a very low risk category suitable for active surveillance 35% of the time. Ten percent of the time low-risk men were reclassified into a higher risk category (5).

Pros: Helps determine the risk of pursuing active surveillance. Improves CAPRA risk assessment accuracy on biopsy and improves the CAPRA-S score for risk of progression free survival determined by prostatectomy pathological grading.

Cons: For biopsy tissue, the accuracy of the test depends on accuracy of the biopsy.

The test is available through your physician by phone (877) 622 6897 and online at http://www.oncotype.com. They help with costs (~ $3,800) and insurance billing.

Prolaris Test (Score)
The Polaris Score (PS) measures the average RNA expression of 31 cell cycle genes that reflect frequency of cell division. The more aggressive the PCa, the faster is the rate of cell division/proliferation and the higher the PS.

Researchers at UCSF found combining the Polaris score (PS) with the CAPRA score improved predictive risk assessment for biochemical recurrence and mortality (6).

Pros: This test, which is performed on biopsy tissue, helps men decide between active surveillance and local treatment. When the test is performed on prostate tissue after surgery, it helps men determine if postoperative treatment is indicated.

Cons: For biopsy tissue, the accuracy of the test depends on accuracy of the biopsy and may add unnecessary expense in following very low risk PCs.

The test is available through your physician by phone (801) 584 1175 and online at http://www.prolaristest.com. They help with costs (~ $3,400) and insurance billing.
Circulation is a vital part of strengthening your immune system’s ability to fight off disease. This is especially true in the case of cancer. Providing a good amount of oxygen to your cells keeps them healthy and increases their resistance to disease. Oxygen also aids in the repair of previously damaged cells. Dr. Dean Foster and Strength Trainer Joseph Aviel are going to show you an exercise that will keep your heart and lungs at the top of their game, circulating as much oxygen as possible to your body.

**Intervals!**

Interval training can be done on a range of equipment. Our machine of choice is the bike. This bike doesn’t go anywhere but if you like to ride, a real bike will work just as well. We will be using a phone to time ourselves, but you can use a watch or just count in your head. Now let’s get some blood pumping! Start with a 30 second warm up. Pedal at a slow and steady pace, being sure not to tire yourself out (yet) but you also don’t want to be going so slow that you fall asleep. Your 30 seconds are up, PEDAL PEDAL PEDAL really fast (but also with moderation) and continue at this pace for another 30 seconds. Now that you’re tired, continue at your warm up pace for another 30 seconds. Starting to catch the pattern? Theoretically you’ll continue this way as long as you want. We recommend 8-10 minutes for your first time as this is equivalent to a much longer session of other cardio exercises.

You’re feeling better already, aren’t you?

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**Snacks or meal replacements:**

If you want to get lots of veggies and rest the digestion, juicing is a great and delicious choice. Alter the ingredients to your taste.

**The Italian Job Juice**

Carrots, tomato, basil, garlic and cayenne pepper. This power juice is full of lycopene, vitamins, calcium and kicks up your metabolism. You choose the level of raw garlic and amount of cayenne. Best to start small and increase as you gain tolerance to the spice and garlic. The sweetness of the carrots balances the acid of the tomato and creates a delicious and refreshing drink. Simply send these through the juicer and enjoy. Use the pulp in your compost or Google for recipes to include for meals and baking ideas. Great additions are red bell peppers, beets, hickama, and any other veggies you love. I personally like red drinks and green drinks for the color appeal rather than mixing and getting a browned color. It is only eye appeal because taste is never compromised. You can also substitute sea salt and powered garlic.

**The Green Giant Juice**

Kale, cucumber, celery, ginger and lemon with a splash of mint. This mighty drink gives you a giant dose of nutrients while helping soothe the digestion with the benefits of ginger root. It’s your choice as to how warm you like the ginger and how mighty you ration the kale. This juice energizes while hydrating and aids digestion. The juicer offers a fiber free rest for your digestive track while saturating you with more nutrients than you possibly can chew. I sometimes just juice the leftover salad from the night before. What an easy way to get the nutrition in.

**Chia Seed Smoothie**

Soaked chia seeds combined with nuts and fruit offer a satisfying and delicious way to bring a naturally satisfying solution to hunger and sweet tooth. Soak the chia seeds overnight and add your favorite fruits or berries and enjoy your personal favorites and what is in season to give the soaked chia seed an endless ability to keep you satisfied and ward off the desire for sugar-based desserts. Protein powder can be added if you are meal substituting or need the added protein. Cinnamon is sprinkled on top for warmth and flavor.
Decipher Test (Genomic Prostate Cancer Classifier)
Researchers at both Johns Hopkins and Mayo have collaborated and confirmed the Decipher “Genomic Prostate Cancer Classifier” can significantly enhance prediction of biochemical recurrence and metastases following radical prostatectomy. The test uses paraffin embedded tissue from the RP specimen to check on 22 genomic biomarkers. It reports a low to high probability of rapid metastatic progression and potential disease specific mortality.

Decipher testing helps high-risk men identify who really needs radiation and/or androgen deprivation therapy. For example, Decipher reclassified 60% of high-risk category men into low risk. They had 2.5 times less risk of metastases. These men could wait before having radiation. Another subgroup in this high-risk category was four times more likely to have rapid metastatic progression and would have elected to receive treatment (7). In another study, when presented Decipher data, 31% of physicians changed their recommendation from treatment to observation in this high-risk group. Decipher has been shown to improve CAPRA prediction of risk (8).

Pros: Helps men who have had surgery decide on need/timing of further treatment. Improves prediction of biochemical recurrence after surgery and whether it will lead to subsequent life threatening rapid metastatic progression.

Cons: Only used on RP specimens. Currently not available unless approved in a trial, available by the end of 2013.

The test will be available by 2014. Follow it online at http://www.prolaristest.com. Cost for QV, ~$600; PV, ~$1,350.

Profile Plus Tests
QuadVysion and ProstaVysion Tests
QuadVysion
Pathologists don’t always agree on Gleason grade or even on whether or not cancer is present (9) Having a pathology second opinion can improve accuracy. Pathologists don’t always agree on Gleason grade or even on whether or not cancer is present. Having a pathology second opinion report on your biopsy grade, PTEN, proliferation Ki67 and DNA Ploidy in summary with clinical relevance needed for guiding patient treatment decisions.

Pros: QuadVysion can help determine presence of cancer when the pathology report is equivocal. ProstaVysion can help determine PCa aggressiveness.

Cons: Does not check surrounding tissue for PCa biomarkers, therefore a negative biopsy may not preclude the presence of cancer.

Both tests are available through your physician by phone (877) 865 3262 and online at http://www.prolaristest.com. Cost for QV, ~$600; PV, ~$1,350.

OurView Prognostic Panel
This panel incorporates clinical factors, Gleason grade, PTEN, proliferation Ki67 and DNA Ploidy in a pathology second opinion report on your biopsy that improves risk assessment and treatment decision-making.

Pros: Helps to resolve equivocal pathology and Gleason grading on the PCa biopsy and helps predict need for treatment. Cost of test is $350.

Cons: For biopsy tissue, the accuracy of the test depends on accuracy of the biopsy.

This test is available by physician at (888.868.7522) and https://www.ourlab.net/OURView_Prognostic_Panel.asp

Tests that Improve PCa Treatment Selection and Efficacy
Caris Molecular Intelligence Profile and Profile Plus Tests
The Caris MI Profile tests are done on tumor tissue from any source. The MI Profile test offers a comprehensive test of over 30 cancer biomarkers to profile PCs and determine the likelihood of response to therapy from its universe of 46 different FDA approved cancer drugs. The MI Profile Plus test adds the Next Generation Sequencing Panel, testing an additional 44 biomarkers.

The Caris tests are part of a service that is especially helpful in difficult to treat cancers like neuroendocrine (small cell) PCs. They suggest novel medications to try that have a high likelihood of helping. In addition, they offer individual tests like P-glycoprotein, an accurate predictor of resistance to chemotherapies like Docetaxel.

Pros: Very flexible and custom biomarker testing platform. Helps oncologist to work “outside the box” for treatment of difficult PCs by suggesting novel medications. The company will help match patients with ongoing clinical trials.

Cons: Because the treatments and biomarkers for PCs are rapidly evolving, clinical trial confirmation of efficacy is limited. Costs are high but insurance is reimbursing. Both tests are available by physician at (866) 771 8946 and at http://www.carislifesciences.com. The company will help with insurance billing. Charges are accepted and reimbursed by Medicare. The MI Profile costs $6,500, the MI Profile Plus $10,000.

Conclusion:
Like other new technologies, the biomarker industry is rapidly evolving/improving. Although expensive, insurance like Medicare have seen their value in guiding men in the difficult decisions they face and are beginning to authorize coverage/payment. The realization of personalized care for a very complicated disease has begun. The implications for improving treatment are profound. The PCRT is committed to reporting this bio-revolution and making its latest advances available to you. (1)

Annual Conference attendees can visit these exhibitors for more information on these tests. (references available online)

The Prostate Cancer World Has Lost a Bright Shining Light
By Mark Scholz, MD
Tom Brodzeller passed away May 14th from complications of a stroke that occurred while he was in the hospital for heart problems. Tom and Ralph Valle have been leading an amazingly vibrant and successful prostate cancer support group in Phoenix for many years. While I have not been privy to the inner workings of the group, I have seen Tom serving as an indefatigable booster and a tremendous force for public relations. Ralph brings tremendous depth of knowledge about prostate cancer giving unbiased direction to men seeking answers. Tom also worked tirelessly helping fellow prostate cancer survivors and was very well versed in the disease.

I knew Tom as a prostate cancer patient. He had one of those confusing “in between” types of prostate cancer that seem to threaten, but even after many years of off and on treatment, never actually led to any direct health problems. At the time Tom died, he was off all therapy with a low PSA. Tom would come and visit me in Los Angeles every six months. Despite his bigger than life personality and in-depth knowledge of prostate cancer he was always deferential. At least as deferential as a gigantic ball of energy can be. He would time his doctor visits to coincide with the need to pass through Los Angeles on the way to taking one of the frequent cruises he so enjoyed.

A very brief synopsis of Tom’s life history has kindly been provided by Ken Cantrell. “Tom was born in Wisconsin in 1937. He attended college at St. Norbert’s in De Pere, Wisconsin. He was a detail man for McNeil Labs prior to starting his own pest control business. Tom was an avid trap and skeet shooter in his younger years and enjoyed bird hunting and fishing. He is survived by his brother, a retired Jesuit priest.”

Tom was one of those rare individuals who are so much fun to be around you always felt bad when he had to go. I know that hundreds of men who have been touched by Tom’s enthusiastic generosity and wisdom will feel exactly the same way. Ralph, who helped start the “Lunch Bunch” support group, has asked Us Too to rename the group, “The Tom Brodzeller Lunch Bunch Support Group.” How appropriate. By the reminder of his name, Tom’s inspiring presence will continue to encourage us all each time the Lunch Bunch is mentioned.
Understanding Survival Statistics

What They Mean – and What They Don’t Mean
By Jan Manarie, PCRI Senior Educational Facilitator

Survival. It’s a huge word. Yet science uses it often, and without pause. It is a statistic. But for the cancer patient, the word survival is more than a statistic. It is one of the most personal statements about him and his cancer journey. It deserves more than common reference, and more understanding of its true definition. For the newly diagnosed prostate cancer patient, survival is one of the first thoughts. But we are still learning how to explain more clearly that every prostate cancer is different, and the majority do not even shorten survival.

For the man with recurrent prostate cancer, the issue of survival resurfaces. Once again, he is wondering if someone can really tell him how long he’ll “survive” with this cancer. Often he is shocked by his own recurrence – perhaps he was told he was “cured”.

For the castrate-resistant (or hormone-refractory) patient, concerns about mortality are even greater. Preoccupation with survival is heightened by media reports of high drug prices coupled with “months” of extended survival. This has accompanied virtually every newly approved prostate cancer drug since 2010, including PROVENGE, Zytiga, Xandi, and now Xofigo. This tends to leave a man trying to do his own personal math – measuring his survival in definitive months or years, based on the small amount of information he has received on “median overall survival”. This article will help show you how that type of calculating almost always underestimates survival.

**“Because survival statistics are based on large groups of people, they cannot be used to predict exactly what will happen to an individual patient…”**

-National Cancer Institute

### Newly Diagnosed & “Survival”

For the newly diagnosed man, survival is often his first thought, and can instill fear for a long time. This fear often leads to a rushed treatment decision, even though it is recommended that a man take time to make his treatment choice. One of the steps in the treatment decision process is to understand what risk category his cancer fits into. (See Aug 2012 PCRInsights – Newly Diagnosed: Understanding Your Risk) Is he High Risk? Intermediate Risk? Low Risk? Or Very Low Risk? The Risk Category calculations most widely used are probably these 3: (1) D’Amico (2) NCCN (3) CAPRA Score. Of these 3, only CAPRA Score measures survival – Progression Free Survival to be exact (at 10 years).

But it is important to remember that many things can change in the 10 years after diagnosis, especially new drug approvals. And even the CAPRA is changing with time and newly available tests. Ongoing clinical trials are currently integrating a prostatectomy pathology testing called Decipher. This test is showing the ability to “down-risk” some men who originally had a High Risk CAPRA Score. [1]

D’Amico and NCCN Guidelines only measure risk of PSA recurrence after surgery or radiation (at 5 years), not survival. So a newly diagnosed man who is in D’Amico or NCCN’s High Risk category, is at high risk of PSA recurrence after surgery or radiation – not at high risk of dying. Although we can argue that the recurrence rates and survival rates are related, they are not synonymous. Many men who have recurrence die from other causes, not prostate cancer. Therefore, it is important that a man understand what he’s being told he’s at risk for.

It is also important to remember that nothing in science is perfect, including statistics. In fact, to illustrate this with statistics themselves – nothing is 100% accurate, including survival statistics. They are meant to be probabilities and calculated estimates based on certain (but not all) variables. One of the leaders in statistical analysis, the National Cancer Institute states it this way – “Because survival statistics are based on large groups of people, they cannot be used to predict exactly what will happen to an individual patient...doctors cannot be absolutely certain about the outcome for an individual patient.” [2]

### Prostate Cancer Recurrence & Survival

Whether a man has PSA-only recurrence (aka biochemical recurrence), or metastatic recurrence after treatment, the issue of survival resurfaces. He is again faced with the question – “How long can I live?”

Once again, there are no exact measurements of survival with recurrence, only statistics. Studies can give estimates, but Dr Marc Garnick from Harvard reminds us, “Remember that average survival times are based on studies of men treated in the past, and sometimes as long as 10 or 20 years ago.”[3] So, they cannot factor in new treatments available after those 10 or 20 years. Table 1 (pg 18) represents the pace of new drug approvals over recent years – treatments which significantly prolong a man’s survival.

Dr Garnick goes on to say that some of the studies that measured survival “…included men who did not undergo further treatment after biochemical recurrence was detected...For these reasons, the “average” chances may be much better for a man treated today.”

### CRPC - Median Overall Survival & The FDA

The FDA considers survival measurement to be the most reliable cancer endpoint for measuring treatment effectiveness. [4] In the 70’s, the FDA required from a clinical trial for a cancer drug to receive its FDA approval.

“...average survival times are based on studies of men treated in the past, and sometimes as long as 10 or 20 years ago.”

-Marc Garnick, MD
Harvard Health Publications

![Median](image_url)
Table 1. FDA Approval & Survival Benefit – Castrate Resistant Prostate Cancer

<table>
<thead>
<tr>
<th>CRPC/ HRPC Drug (generic name) year</th>
<th>TYPE OF Drug</th>
<th>MEDIAN OVERALL SURVIVAL Benefit</th>
<th>RISK OF DEATH Reduced by</th>
<th>When Compared To</th>
<th>Previous Taxotere?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taxotere (docetaxel) 2004</td>
<td>Chemotherapy (IV drip)</td>
<td>2.5 mos</td>
<td>24% (7)</td>
<td>mitoxantrone (other chemo)</td>
<td>NO</td>
</tr>
<tr>
<td>Jevtana (cabazitaxel) 2010</td>
<td>Chemotherapy (IV drip)</td>
<td>2.4 mos</td>
<td>30% (11)</td>
<td>mitoxantrone (other chemo)</td>
<td>yes</td>
</tr>
<tr>
<td>PROVENGE (sipuleucel-T) 2010</td>
<td>Immunotherapy (pheresis + IV drip)</td>
<td>4.1 mos</td>
<td>22.5% (9)</td>
<td>Placebo, then PROVENGE</td>
<td>Some yes, Some NO</td>
</tr>
<tr>
<td>Zytiga (abiraterone) 2011</td>
<td>Secondary hormonal therapy (pills)</td>
<td>3.9 mos</td>
<td>35% (10)</td>
<td>Placebo</td>
<td>yes</td>
</tr>
<tr>
<td>Zytiga (abiraterone) 2012</td>
<td>Secondary hormonal therapy (pills)</td>
<td>4.6 mos</td>
<td>25% (11)</td>
<td>Placebo</td>
<td>NO</td>
</tr>
<tr>
<td>Xtandi (enzalutamide) 2012</td>
<td>Secondary hormonal therapy (pills)</td>
<td>4.8 mos</td>
<td>37% (11)</td>
<td>Placebo</td>
<td>yes</td>
</tr>
<tr>
<td>Xofigo (radium 223) 2013</td>
<td>Injectable radiation for bone (injection)</td>
<td>3.6 mos</td>
<td>30.5% (13)</td>
<td>Placebo, Some yes, Some NO</td>
<td></td>
</tr>
</tbody>
</table>

Since 2010, we have seen several drugs receive FDA approval for men with castrate resistant prostate cancer. Each time a drug is approved, the Median Overall Survival benefit is quoted (see Table 1). This leaves men and their families thinking this is a finite number that applies to them personally and often trying to weigh out the months of promised life against the expensive price tag associated with the new drug. Since these are the 2 numbers that inevitably make the news, this type of “math” is not surprising. However, let me shed more light on more numbers which should help give a broader perspective and change up the mathematics a little.

When a drug is FDA approved, the pharmaceutical companies are highly regulated in what they can print and say. For example, they are not allowed to make claims about their drug that weren’t in the published Product Information (PI) document approved by the FDA. The PI document may quote the Median Overall Survival, but usually doesn’t mention the mean (average) or the range in overall survival from the studies. So MOS is often the only number we’re given, although some companies have found an alternative FDA-approved way to report their data. In Figure 2, Dendreon, the manufacturer of Provenge, illustrates the percentage likelihood of increased survival three years in the future compared to men who were treated with placebo.

Fear of Death

This is a difficult subject to discuss but since I was forced to face it head-on for 13 years with my husband, it is something I’m ready to talk about. Dominic lost his cancer battle in April 2013 – 13 years and 1 month after his diagnosis of widely metastatic prostate cancer. This type of journey brings out every emotion you can name, and magnifies them at times. Some of them are familiar – some of them are a surprise. But the one emotion I had to face most over those 13 years was simply fear. Fear of losing my husband – fear of my son losing his father – and every other fear that goes with it. Sometimes I would retreat to deal with the feelings. Often I would pray. But, I was a busy caretaker, so long car rides to do errands often became my getaway. I did find this one simple truth; facing my fears made me a better advocate for my family. But I had to retreat to do it. Running away from my fears only made me more anxious and fearful. I believe that facing your fears is an important element of patient empowerment and especially advocacy. It makes you stronger, not weaker. Find some time to do this for yourself and the ones you love.

Defying the Odds

The prostate cancer community is full of men who have beaten the odds, defying the statistics makes cannot be measured. Yet they are very real.

Things We Cannot Measure

As Dr Garnick pointed out previously, studies cannot measure everything. They cannot measure the impact of new treatments that will come to market years after the statistics were published. They cannot measure the advocacy of a wife or family member and the impact it has on choosing better treatments. They cannot measure the positive choices a cancer patient makes in his journey, such as dietary and lifestyle changes, preventing side effects or speaking up at a doctor’s appointment. As the National Cancer Institute pointed out, nothing in science is perfect, including statistics. They are probabilities and excellent percentages. However that is still different than perfection. The power of future changes, and the choices a cancer patient

2013 Prostate Cancer Run Results - Los Angeles

PCRI would like to thank everyone who came out to help raise awareness at Dockweiler State Beach on July 20th! This year, PCRI teamed up with Urologist Specialists of Southern California and ZERO - The End of Prostate Cancer for our second annual Prostate Cancer Run.

The race is part of the Great Prostate Cancer Challenge, America’s Premier Men’s Health Event Series, and taking place in 38 cities nationwide in 2013 with the mission of raising awareness and funds to provide research and free testing. In 2012, the race series attracted more than 18,000 participants and raised more than $2.1 million for advocacy toward prostate cancer research, providing early detection and spreading education and awareness.

**Male Podium**
1st Alec Borsook
2nd Dan Kuch
3rd Sean Gardner

**Female Podium**
1st Andrea Young
2nd Olivia May
3rd Lisa Uhrig

**Top Survivors**
1st Jeff Glasser
2nd Philip Toomey
3rd Jeremiah Crowley

(Continued on next page)
they were quoted by their physicians. I will continue to argue that getting involved in your cancer care, or “patient empowerment”, is one of the most significant factors. This is based on what I have seen in 11 years on Helpline and 13 years of advocating for my husband who was diagnosed with a PSA of 7,096. He had extensive bone mets for all those years – and again, lived for 13.

We beat all odds and every statistic you could throw at us. I knew his medical records, listened to his needs and desires, and was greatly responsible for ordering tests and choosing treatments. This was because we had a wonderful oncologist who listened to us and knew how our situation was different, including my job and my involvement in advocacy. His expertise guided us, but ultimately Dominic was in the lead. We often changed decisions on a weekly basis simply because that’s what Dominic needed or wanted. We listened to him, and we listened to his medical records – key to patient empowerment.

Here are more stories from men who have castrate resistant prostate cancer and have beaten the odds. Most of them also have metastatic disease. These men are part of a longstanding Email Support Group, which you can find on www.HRPCA.org. I have been a long-time member. So have many other great advocates and warriors.

Personal Stories – Beating the Odds

- **Donald & Nancy** - “Yes indeed, I was “given” 3-5 years - more than 10 years ago and I’m still rolling along fine.”
- **Dan J** - “I was given a year, five and half years ago,”
- **Jan Burgess** - “Gord was given 6 mos – 13.5 years ago!!”
- **Joyce O.** - “My husband isn’t here to testify, but he lived 15 years after his diagnosis. He was told he had 2-3 years to live by a radiation oncologist...He didn’t die of prostate cancer 15 years later, but of a heart attack. I felt he lasted so long because of our research of all the effective treatments that were available....Keep on fighting!”
- **Kirby B** - “I was given 16-24 months on diagnosis Feb. 7, 2000. PSA was 87 with spread to pelvic lymph nodes. I am now 13 years out and still golfing.”
- **Don Q** - “I am pleased to report that I have now achieved my 15th year since diagnosis of PCs ... Doc told my wife 18 months,...Survival largely due to doing research and finding the right Docs, treatments and medicines, natural and otherwise. Fortunately still fairly fit and enjoy life. Regards”
- **Ron A** - “At diagnosis Gleason 9’s and a PSA of 12.8, I was told that my Ca was advanced and aggressive and that the only option was hormonal palliative care. That without it I would be dead in two years. It will be 7 years in November since I was diagnosed ...If I could advise any of you of one thing it is to watch your weight, diet and exercise. We more often die of heart disease before the cancer gets us.”
- **Michael J.** - “I was diagnosed with Stage IV metastatic Ca on December 23, 1999 and given less than 9 months to live....Doc. Myers has fought two recurrences with me and I am working part time and living a very active life. I am writing from the French Countryside where I played golf yesterday. Never give up!”

Let this article be a reminder that survival statistics are never perfect and were never intended to be. Let it also be a reminder that people truly beat the odds every day, and becoming involved in your treatment decisions is one of the most powerful factors in beating any odds or statistics that were quoted to you. ☐

Come hear Ian speak at the September 2013 Conference – see agenda page 22.

(references online)
Saturday, September 7, 2013

General Sessions

Faculty

Charles Myers, MD
Medical Oncologist
American Institute for Diseases of the Prostate

Nicholas Vogelzang, MD
Medical Oncologist
Comprehensive Cancer Centers of Nevada

Mack Roach III, MD
Chairman of Radiation Oncology, UCSD

Timothy Wilt, MD
Internal Medicine Physician, Veterans Affairs Medical Center

Timothy Wilt, MD
Chairman of Radiation Oncology, UCSD

Duke Bahn, MD
Medical Director, Prostate Institute of America

Mark Scholz, MD
Medical Director, Prostate Oncology Specialists

Charles Drake, MD, Ph.D
Associate Professor of Oncology, Johns Hopkins University

Mark Kawachi, MD
Clinical Associate Professor of Urological Oncology City of Hope

Sunday, September 8, 2013

Ask the Experts (2 sessions)

Faculty

Steven Finkelstein, MD
Radiation Oncologist, Director TRC
21st Century Oncology

Jeff Turner, MD
Medical Oncologist, Prostate Oncology Specialists

Mark Scholz, MD
Active Surveillance & Focal Therapy

Verne Varona
National Author

Charles Myers, MD
Hormone Therapy

John Kurhanewicz, Ph.D.
Professor of Radiology and Biomedical Imaging, UCSF

Charles Drake, MD, Ph.D
Immunotherapy

Mark Kawachi, MD
Surgery

Sunday, September 8, 2013

Roundtable Discussion

Faculty

Various Speakers
Case Studies

Conference Moderator:
Mark Moyad, MD, MPH
Jenkins/Pokemperni Director of Complementary & Alternative Medicine
Univ of MI Med Center-Dept of Urology

Sunday, September 8, 2013

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- Friend: $50

PLUS: Back by popular demand: Jerry Peters and Friends will once again perform along with a keynote by David Hung, M.D., President/CEO, Medivation at the Saturday Night Dinner Gala!

Facility and agenda subject to change.
Please visit www.PCRI.org for updated faculty, registration and travel information.
You may also register online by visiting www.PCRI.org, or by calling the PCRI office at 310-743-2116.

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**Prostate cancer will strike 1 in 6 men. Your generous donation helps us fight prostate cancer through research, education and increasing public awareness.

The official conference hotel is the Marriott LAX Airport Hotel located at 5855 W. Century Blvd., Los Angeles, CA. A limited number of discounted rooms are available for $95/night by calling 310-641-5700 and mentioning group code NCPNCPA, or by visiting www.PCRI.org for an online booking link. This group rate is available only until August 14, 2013.

Discounted airline tickets to/from LAX are available by calling American Airlines at 800.433.1790 or visiting www.aa.com. Use group code A5793BH.

Self-parking at the venue is $10/day and valet parking is $25/day. Complimentary hotel shuttles are available at LAX (under the red sign).

Cancellations and refund requests will be honored only if made in writing no later than August 15, 2013.

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Saturday Night Fun: Jerry Peters and Friends

Due to the overwhelming popularity of last year’s performance, Grammy Award-winning musician Jerry Peters will return to perform at the Saturday Night Dinner Gala!

Meet the Speakers

Get up close and personal with the prostate cancer experts. Ask your questions in person, make new friends, and enjoy Los Angeles.

DON’T MISS THIS OPPORTUNITY!

September 6-8