

THE MANITOBA PROSTATE CANCER SUPPORT GROUP NEWSLETTER



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Current Issues In Hormone Therapy

There are many issues around hormone therapy that not all doctors agree on, such as the best time to start and stop it and the best way to give it. Studies are now looking at these issues. A few of them are discussed here.

Treating early stage cancer: Some doctors have used hormone therapy instead of watchful waiting or active surveillance in men with early (stage I or II) prostate cancer who do not want surgery or radiation. Studies have not found that these men live any longer than those who do not receive any

treatment at first, but instead wait until the cancer progresses or symptoms develop. Because of this, hormone treatment is not usually advised for early stage prostate cancer.

Early versus delayed treatment: For men who need (or will eventually need) hormone therapy, such as men whose PSA level is rising after surgery or radiation or men with advanced prostate cancer who do not yet have symptoms, it is not always clear when it is best to start hormone treatment. Some doctors think that hormone

therapy works better if it is started as soon as possible, even if a man feels well and is not having any symptoms. Some studies have shown that hormone treatment may slow down the disease and perhaps even lengthen survival.

But not all doctors agree with this approach. Some are waiting for more evidence of benefit. They feel that because of the likely side effects of hormone therapy and the chance that the cancer could become resistant to therapy sooner, treatment should not be started until a man has symptoms from

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Thanks!

NEXT MEETING: April 18, 2013

Gayle Nichol

C.R.N. at MB. Prostate Centre

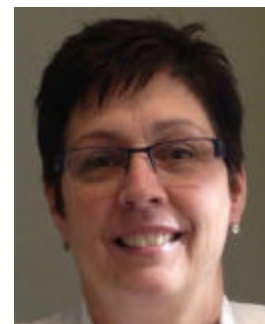
“Living with Androgen Deprivation”

Location: Seven Oaks General Hospital

Main Floor Auditorium

Leila & McPhillips

Time: 7:00 PM to 9:00 PM



The Manitoba Prostate Cancer Support Group does not recommend treatment modalities, medications, or physicians.

Thought For The Day

“A man’s life is dyed the color of his imagination.”

Marcus Aurelius

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the cancer. Studies looking at this issue are now under way.

Intermittent versus continuous hormone therapy: Nearly all prostate cancers treated with hormone therapy become resistant to this treatment over a period of months or years. Some doctors believe that constant androgen suppression may not be needed, so they advise intermittent (on-again, off-again) treatment.

In one form of intermittent therapy, hormone treatment is stopped once the PSA drops to a very low level. If the PSA level begins to rise, the drugs are started again. Another form of intermittent therapy uses hormone therapy for fixed periods of time – for example, 6 months on followed by 6 months off.

Clinical trials of intermittent hormonal therapy are still in progress. It is too early to say whether this new approach is better or worse than continuous hormonal therapy. However, one advantage of intermittent treatment is

that for a while some men can avoid the side effects of hormonal therapy such as decreased energy, impotence, hot flashes, and loss of sex drive.

Combined androgen blockade (CAB): Some doctors treat patients with both androgen deprivation (orchiectomy or an LHRH agonist or antagonist) plus an anti-androgen. Some studies have suggested this may be more helpful than androgen deprivation alone, but others have not. Most doctors are not convinced there's enough evidence that this combined therapy is better than one drug alone when treating metastatic prostate cancer.

Triple androgen blockade (TAB): Some doctors have suggested taking combined therapy one step further, by adding a drug called a 5-alpha reductase inhibitor – either finasteride (Proscar) or dutasteride (Avodart) – to the combined androgen blockade. There is very little evidence to support the use of this "triple androgen blockade" at this time.

"Castrate resistant" vs. "hormone

refractory" prostate cancer: These terms are sometimes used to describe prostate cancers that are no longer responding to hormones, although there is a slight difference between the two.

"Castrate resistant" means the cancer is still growing despite the fact that hormone therapy (either an orchiectomy or an LHRH agonist or antagonist) is keeping the testosterone in the body at very low, "castrate" levels. Some men may be uncomfortable with this term, but it is specifically meant to refer to these cancers, some of which may still be helped by other forms of hormone therapy (and are therefore not completely "hormone refractory"). "Hormone refractory" refers to prostate cancer that is no longer helped by any type of hormone therapy, including the newer medicines.

Last Medical Review: 02/27/2012

Last Revised: 01/17/2013

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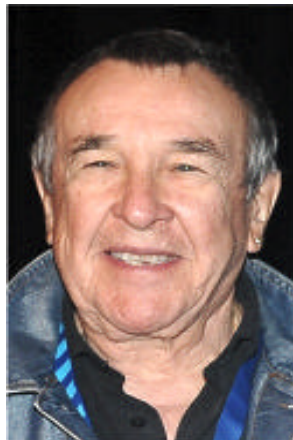
In Memory

Norm Oman passed away February 21, 2013. Funeral services were held on February 25th at Shaarey Zedek Synagogue in Winnipeg.

Norm was diagnosed with prostate cancer in 1992 and was instrumental in starting the Manitoba Prostate Cancer Support Group in the same year. He served as Chair twice: 1993 - 1995 and also 1999 - 2008. During this time, Norm was heavily involved with establishing the Prostate Centre at Cancer Care Manitoba.

In 1995, Norm became a regional director in western

Canada of Us Too International, served on their Board of Directors and was also one of the founding members of the Canadian Prostate Cancer Network (CPCN).



At the national Prostate Cancer Canada Network (PCCN) conference held in Toronto in 2010, Norm was presented with their Founder's Award recognizing his service, leadership, innovation and integrity.

Norm had an outstanding record of achievement within the Support Group community and was highly respected for his many accomplishments. We mourn his passing and extend our deepest sympathy to his family.

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Active Surveillance: Q & A with Dr. Laurence Klotz

Toronto Sunnybrook Health Sciences Centre's Laurence Klotz, MD, speaks with PCRI about management of low-risk prostate cancer with Active Surveillance.

What is active surveillance, and how does it compare with other methods of treating prostate cancer?

The concept of conservative management for prostate cancer is not new. In fact, in Scandinavia and England in the 70s, basically no one was treated until they had metastatic disease. And the idea was that treatment didn't really have much effect; this was a slow-growing disease and people didn't die from it. We now know that is wrong in many respects, and so the idea of no treatment has pretty much been abandoned.

When PSA emerged around 1989, and suddenly all this early prostate cancer was being diagnosed, the idea was that many of these patients harbored aggressive disease and should be treated radically. And virtually all newly diagnosed men in the United States, Canada and most of the Western world were offered aggressive treatments for their disease.

But not everyone with prostate cancer is destined to die from it, and the real problem with PSA screening that should be addressed is the over-diagnosis of clinically insignificant disease.

The crux of the problem is that the likelihood of harboring small bits of prostate cancer in a man is about equal to his age as a percentage. So that means in men who are, say, between 50 and 70 - which is the key age group for diagnosing and treating prostate cancer - somewhere around 60 percent will have small bits of prostate cancer. And many of them will have an elevated PSA, due, for example, to benign prostatic enlargement. This

leads to a biopsy, and the biopsy finds these little bits of prostate cancer. And these patients were all getting radical treatment, even though what they had was (in my view) really part of the aging process, something that develops more or less normally in men with age.

The active surveillance was an attempt to grapple with this by saying, okay, we know that guys who have bad prostate cancer need treatment, and benefit from it. And that's been clearly shown in randomized trials. But the patients dying of prostate cancer tend to have higher grade (Gleason) cancer. So maybe we can take the ones who have low-grade cancer, just manage them conservatively, and keep a close eye on them because some may develop something worse. We can then treat those who get reclassified as having higher risk disease, and observe the rest. So we started doing that around 1996, more than 15 years ago. At the time, it was considered very experimental, and patients had to sign an informed consent form that they were going on a clinical trial. Yet patients flocked to this approach, because word was getting out that there were problems with the outcome of surgery and radiation in terms of quality of life.

And so, cycle forward about 15 years, there's now about 4,000 men reported in the world literature that have been followed prospectively this way, and hardly anyone dies of prostate cancer (in the range of 1 percent).

The vast majority of men who are found to have these little bits of low-grade cancer have absolutely no threat to their life, and can be managed with conservative treatment. A few of them, however, harbor worse disease. It's just missed on the biopsies, so the biopsy needle just gets a glancing blow off the edge of a large cancer, and it shows up as a small amount of low-grade disease. So you have to repeat the biopsy once in

a while, you have to follow the PSA, and there's other techniques like multiparametric MRI that may come into play.

But the basic concept is that most of these men don't have a real disease at all - they have something that's a normal part of the aging process, and doesn't need to be treated. That's now very robust I would say, and most people accept this. It's been a tremendous boon to men to give them the opportunity to avoid the side effects of treatment.

What makes a patient a good candidate for active surveillance?

The main candidates for active surveillance, the patients for whom there is very little controversy, are guys who have a mildly elevated PSA, preferably less than 10, and whose biopsy shows relatively small amount of Gleason 6 prostate cancer.

What do you recommend for men going on an active surveillance program, as far as self-care?

We know that a diet that is good for your heart and that's good for your prostate is the same diet. So I advise men to watch their weight, avoid too much animal fat and red meat, and reduce caloric intake to some degree.

And for the men who want to be proactive, I think it's reasonable to be on some micronutrients, like lycopene, vitamin D, and perhaps a statin.

How do you monitor for progression?

Patients need to have a second biopsy, and we usually wait around 9 to 12 months to do that. The reason to wait is mainly to give them a break, because most men aren't too thrilled with the idea of another biopsy. We monitor the PSA every three months for the first two years, and then every six months. Although the PSA is

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not reliable as a trigger for intervention, it is a guide. For example, in our series, the patients who did badly all had a very rapid rise in PSA. The problem is, so did a lot of other guys that did perfectly well. So it is a flag, but not a trigger. They have the biopsy within a year, which targets the areas that tend to get missed on the first biopsy, and that's very important.

In a normal transrectal diagnostic biopsy, the anterior (the front part of the prostate) doesn't get evaluated very well, which is not usually a problem because most cancers aren't in that area. But in the surveillance population, a few of them do have these large anterior cancers. So the confirmatory biopsy targets the area of the prostate that tends to get missed in the initial biopsy. And if that's negative, or shows the same thing, then the frequency really falls off and we biopsy the patients around every four years.

And when they reach age 80, we stop.

The multiparametric MRI has emerged recently as a very powerful tool in managing patients on surveillance. We don't do it with everyone. But if a patient has a significant increase in the volume of Gleason 6 cancer on their repeat biopsy, or what looks like worrisome PSA kinetics, or if there's Gleason 3 plus a small amount of 4 and the question is 'how much disease does the patient have?' the MRI is very useful. So that's our basic monitoring strategy.

NOTE:

The National Institute of Health defines the difference between Active Surveillance and Watchful Waiting as such:

"Active Surveillance is a disease management strategy that delays curative treatment until it is warranted based on defined indicators of disease progression.

In contrast, Watchful Waiting is a disease management strategy that forgoes curative treatment and initiates intervention only when symptoms arise."

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Hormonal Therapy for Prostate Cancer

Overview

Testosterone is a male hormone produced mainly by the testicles. Many organs in the body are composed of cells that respond to or are regulated by exposure to testosterone. Cells in the prostate have testosterone receptors and when exposed to testosterone, are stimulated to grow. When cells that have testosterone receptors become cancerous, the growth of these cancer cells can be increased by exposure to testosterone. The basis of hormone therapy as a treatment for prostate cancer is to block or prevent the cancer cells from being exposed to testosterone. Hormone therapy is primarily cytostatic (it prevents cancer cells from growing) not cytotoxic (kills cancer cells). Chemotherapy and radiation therapy are cytotoxic treatments. There are two methods of delivering hormone therapy: 1) surgical orchiectomy and 2) medical hormone therapy.



Orchiectomy

Bilateral orchiectomy (castration) is surgical operation to remove the testicles. By removing the testicles, the main source of male hormones is removed and hormone levels decrease. Orchiectomy is a common treatment for patients with metastatic (stage IV) prostate cancer who will likely require hormone therapy for life. Patients may experience a benefit in symptoms in a matter of days following surgery. Orchiectomy can cause side effects such as loss of sexual desire, impotence, hot flashes, and weight gain. The operation itself is relatively safe and not associated with severe complications.

Orchiectomy is a convenient and less costly method of hormone therapy; however, it is irreversible.

Medical Hormone Therapy

The second method of hormone therapy is to take medicines that produce the same effect as an orchiectomy. The medicines that reduce male hormone levels are called LHRH analogues and antiandrogens. Female hormones such as estrogens can also reduce male hormone levels, but can also cause serious side effects and are therefore rarely used.

LHRH Analogues: Drugs that act like luteinizing hormone releasing hormone (LHRH) are known as LHRH analogues. These drugs turn off the signal for testosterone production by the testicles. By turning off the signal, hormone levels are reduced and cancer cells are not exposed to male hormones. LHRH analogues are given as a small injection under the skin of the abdomen every month or every three months. These drugs work just as effectively against prostate cancer as bilateral orchiectomy.

LHRH analogues can cause side effects such as loss of sexual desire, impotence, hot flashes and the development of osteoporosis, which increases the risk of bone fractures. Because these drugs require an injection every 1 or 3 months, LHRH analogues may not be as convenient as an orchiectomy. Unlike orchiectomy, these drugs can be discontinued, and male hormone levels gradually return to normal.

Bisphosphonates are a group of agents that have demonstrated the ability to reduce bone loss in cancer patients with hypercalcemia, bone metastases, Paget's disease or osteoporosis. This prompted

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researchers to conduct a clinical trial evaluating the bisphosphonate Aredia® (pamidronate) in patients with prostate cancer undergoing hormonal therapy with a GnRH agonist.

In this clinical trial, 41 patients had either advanced or recurrent prostate cancer, with no spread of cancer to the bones. All patients were receiving treatment with leuprolide, a GnRH agonist, and half of the patients also received Aredia® during treatment. Measurements of bone density of the lumbar spine, trochanter (top of the femur) and hip were taken prior to initiation of the trial and approximately one year following treatment. Patients who were treated with leuprolide alone had a significant decrease of bone density in all measured areas. Conversely, patients who received the combination of leuprolide plus the bisphosphonate experienced no significant density change in any measured area.

LHRH analogues may be used to treat patients with any stage of prostate cancer. When first taken, these drugs may increase prostate cancer growth and make a patient's symptoms worse. This temporary problem is called "tumor flare." Gradually, these drugs cause hormone deprivation, shrinkage of prostate cancer, and improvement in symptoms. This "tumor flare" can be prevented by taking an antiandrogen medication before LHRH analogues. Antiandrogens are discussed below.

Antiandrogens: Not all male hormones are made by the testicles. A small amount of male hormone is made by the adrenal glands, and may not be affected by bilateral orchiectomy or LHRH analogues. An antiandrogen is a medication that can block the effect of the remaining male hormone on prostate cancer cells. Antiandrogens are pills often given to

patients in addition to orchiectomy or LHRH agonists. This combination of treatment is known as total or combined androgen blockade.

Several clinical studies have directly compared total androgen blockade with a single form of hormone therapy (LHRH analogue or orchiectomy) for patients with metastatic prostate cancer. Two large studies conducted in the U.S. and Europe have shown improvement in disease control and survival with total androgen blockade. In one study involving 603 patients, half the patients treated with a LHRH analogue were alive at 28 months and half the patients treated with combined androgen blockade were alive at 35 months. Most doctors feel combined androgen blockade controls disease and improves survival better than either an LHRH analogue or orchiectomy alone.

Antiandrogens can cause side effects such as loss of sexual desire, diarrhea, enlargement of the breasts and occasional impotence. When used alone, these drugs appear to cause impotence much less often than other forms of hormone therapy. On rare occasion, these drugs can cause liver abnormalities, and blood tests can help detect these problems before serious side effects occur. These drugs can also be discontinued, and male hormone levels gradually return to normal.

When to Start Hormonal Therapy

There is general agreement that men experiencing symptoms from prostate cancer should begin treatment immediately. There has been some disagreement, however, regarding the best time to start hormonal therapy in asymptomatic patients. Researchers from London recently conducted a clinical trial comparing the timing of hormone therapy. Almost 1,000 men participated in the clinical study. Half received immediate hormonal therapy and half had hormonal therapy deferred until they developed symptoms. Patients treated with immediate hormonal

therapy lived longer without cancer progression and were less likely to develop significant complications from cancer.

Strategies to Improve Treatment

The progress that has been made in the treatment of prostate cancer has resulted from improved development of radiation treatments, surgical techniques, development of hormonal therapies, and participation in clinical trials. Future progress in the treatment of prostate cancer will result from continued participation in appropriate clinical trials.

Intermittent Therapy: Some doctors believe that using medical hormonal therapy intermittently can decrease the cost and reduce the side effects of treatment. When treatment is withheld for a period of time, sexual function and quality of life may improve. It is currently unknown whether intermittent hormonal therapy will provide the same survival benefit as early continuous hormonal therapy.

Combination Therapy: Recently, researchers in England conducted a clinical trial evaluating treatment consisting of hormone therapy plus the chemotherapy agent mitozantrone versus hormone therapy alone for patients with locally advanced prostate cancer. Hormone therapy in this trial consisted of injections of an agent that reduced the production of androgens (particularly testosterone) in the body. Ninety-five percent of patients who received the combination treatment experienced a complete or partial disappearance of their cancer, compared to only 53% of patients who received only hormone therapy. Importantly, the average duration of survival following therapy was significantly higher in patients who received both Novantrone® and hormone therapy, nearly 7.5 years, compared to 3 years for patients receiving only hormone therapy.

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Caring for Your Bones When You Have Prostate Cancer

Many men experience bone loss and joint pain related to their prostate cancer. Communicating with your health care team is important to maintaining healthy bones. There are also lifestyle changes you can make to help keep your bones strong. This fact sheet answers some commonly-asked questions about prostate cancer and bone health. It also discusses steps you can take to care for your bones.

What causes bone problems when you have prostate cancer?

Bone loss can result from your treatment. Testosterone, the male sex hormone, fuels the growth of prostate cancer. Hormone therapy slows cancer's growth by lowering the body's production of testosterone or blocking it from entering cancer cells.

However, the lack of testosterone can weaken bones and put men with prostate cancer at increased risk for fractures. Radiation, chemotherapy, and some pain medications can decrease bone strength as well.

Men with prostate cancer are at risk for bone metastases. Sometimes, prostate cancer travels to other parts of the body. The most common place for

it to spread is to the bones, and this can cause bone pain and fractures. The bones most often affected are the spine, hips and ribs. However, bone pain does not always mean that cancer has spread to the bones. Other conditions can cause it. If prostate cancer has spread to your bones, there are many treatment options that can improve your quality of life.

What treatments are available to strengthen and repair my bones?

Bone loss from cancer treatments is treatable. Your doctor may prescribe medicines called bisphosphonates to prevent thinning of the bones. Oral bisphosphonates approved for treating osteoporosis include alendronate (Fosamax) and risedronate (Actonel). An intravenous, or IV, bisphosphonate called zoledronic acid (Zometa) is also available. It has been shown to reduce bone loss and increase bone strength in men receiving treatment for prostate cancer.

Bone metastases can also be treated. Treatment options include hormone therapy and radiation to treat the cancer, and surgery to repair bones that have been damaged. Zoledronic acid can also be used.

Consider enrolling in a clinical trial for additional treatment options. Clinical trials are studies that test new treatments to prove that they are safe and effective. New treatments are also compared to the standard treatments to see if they are better. An example of a bone health drug in clinical trials is denosumab. It is being tested in men experiencing bone loss due to hormonal therapy for prostate cancer.

What steps can I take to care for my bones?

Schedule an annual bone exam. Bone density scanning, also called DXA or bone densitometry, is the best way for doctors to measure your bone mineral density (BMD). BMD is a measure of bone strength. It is important to get this test before starting hormone therapy so it can serve as a "baseline" of your bone health. This lets your doctor compare your results over time and see how your treatment may be affecting your bones.

Make your dentist part of your health care team. If possible, visit your dentist for a complete oral exam before starting treatment. During and after treatment, continue to see your dentist regularly. As always, practice good oral hygiene with regular brushing and light flossing, and avoid mouthwash that contains alcohol.

Strive for a healthy diet. Your bones especially need calcium and vitamin D to stay strong. Low-fat dairy products, like milk and cheese, are good sources of calcium. So are dark leafy greens and beans. Fatty fish such as salmon, tuna and sardines are a good source of vitamin D. Ask your doctor about the benefits of vitamin D and calcium supplements.

Make exercise part of your routine. Exercise maintains bone strength and reduces the loss of calcium in your bones. Regular, weight-bearing exercise, such as walking or light weightlifting is recommended. Such activities encourage your bones to strengthen. Try doing some exercise outdoors, as sunshine is a source of vitamin D. It's important not to injure your bones, though. Talk to your doctor about the right kind of exercise for you.

Source: www.cancercare.org

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Whole-Blood, 6-Gene Prognostic Signature May Help Personalize Prostate Cancer Treatment

By William K. Oh, MD, and Yixuan Gong, PhD

Published Online: Monday, February 18, 2013

Prostate cancer is the most common cancer and second leading cause of cancer-related death in men in the United States. Though most patients with advanced disease initially respond to surgical or chemical depletion of serum testosterone, prostate cancer invariably progresses despite castrate levels of testosterone, a clinical state known as castration-resistant prostate cancer (CRPC). Ten to twenty percent of patients with prostate cancer develop CRPC within approximately 5 years of follow-up. CRPC is a strikingly heterogeneous disease state, and as a result, the overall survival of patients can range from a few months to many years. The ability to accurately predict prognosis in CRPC is critical for patient counseling and treatment decision making.

Traditionally, prognosis is based on clinical and laboratory variables, such as age, functional status, extent of bone and other metastases, prostate-specific antigen, alkaline phosphatase, and lactate dehydrogenase. More complicated nomograms have also been developed to combine these individual variables, but only offer moderate predictive power. A large number of immunohistochemistry-based prognostic tissue biomarkers have been proposed; however, a vast majority of these are not used in clinical practice, probably due to the lack of standardized methods to perform and interpret immunohistochemistry, the influence of tumor heterogeneity, and the lack of adequate tissues. There remains an urgent need to develop new prognostic models in CRPC.

Interactions between blood cells and the peripheral tissue through which blood circulates, including neoplastic tissue, might alter the gene expression of blood cells. Indeed, recent studies have shown that gene expression profiling of peripheral blood cells could yield

diagnostic and prognostic information regarding various disease states. Expression profiling of whole blood offers several practical advantages compared with profiling tumor tissue, including the minimally invasive nature of sample acquisition, relative ease of standardization of sampling protocols, and the ability to obtain repeated samples over time.

We profiled the expression of 169 inflammation and prostate cancer-related target genes in whole blood of an initial cohort of 62 patients with CRPC. After using logistic regression and latent class methods to develop models, we were able to identify a 6-gene expression signature consisting of ABL2, SEMA4D, ITGAL, C1QA, TIMP1, and CDKN1A to separate men with low-risk and high-risk CRPC (7.8 months vs >34.9 months survival). A validation study of 140 additional patients confirmed these findings. Further analysis also showed that the prognostic ability of the 6-gene model was superior to clinicopathological variables (Lancet Oncol. 2012;13[11]:1105-1113). The Leon and Norma Hess Center for Science and Medicine, Mount Sinai's newest building, houses many of The Tisch Cancer Institute's research and clinical facilities.

The successful validation of the whole-blood, 6-gene prognostic signature suggests that the host immune response is an important determinant of overall survival in patients with prostate cancer. We believe that this signature can be used not only as a prognostic marker, but also as criteria to stratify patients for some clinical trials. For example, one of the most exciting new developments in the treatment of patients with genitourinary cancers is the use of vaccines and immune-modulators, in particular with prostate and bladder cancers. At the Tisch Cancer Institute at Mount Sinai Medical Center, we

have developed a program around sipuleucel-T, an immune treatment for prostate cancer. Our immune-based 6-gene signature may help to stratify patients and monitor the immune response to the therapy.

Our team is validating and refining the whole-blood prognostic signature using additional cohorts of patients with prostate cancer, conducting studies exploring the evolution of the signature during the course of a patient's illness, and determining the predictive ability of this signature in patients with prostate cancer treated with immune-based therapies. Since it is possible that this signature is not unique to patients with prostate cancer, we are planning to look at the feasibility of the 6-gene signature in other types of malignancies. In the long run, we hope to validate the signature in larger validation cohorts and prospective trials, and eventually incorporate the signature into part of the personalized therapies for prostate cancer patients.

...

Crabby Road

3-19-09



The Manitoba Prostate Cancer Support Group has been providing services for 20 years:

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Many Thanks

Our Prostate Cancer Support Group would like to acknowledge a recent donation from AbbVie Corporation. AbbVie produces Lupron, a drug used for prostate cancer hormone therapy. We are grateful they have chosen to assist us with our work again this year and their kindness is much appreciated. Their involvement helps us to continue our services to the community and we thank them for their generosity.



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SPEAKERS:

May 16, 2013

Kelli Berzuk BMR-PT, MSc, PhD

Pelvic Floor Physiotherapist

"Fireside chat on the Pelvic Floor Muscle"

June 20, 2013 TBA

All meetings are held at
Seven Oaks General Hospital Auditorium
7-9 p.m.
Everyone welcome

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