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PERSPECTIVE

Peter Scholz,
Communications
Manager &
Insights Editor

Knowledge is the synthesis of ideas from many sources and perspectives: What your doctor knows and says, what your own experience and values tell you, what organizations like PCRI say, what the guy at the local support group says, and many more. They are all good, however, none tell the whole story.

And you, the researcher, synthesize a bigger picture from all of these perspectives by combining what your doctor knows with the knowledge you have acquired from other sources while factoring in your personal preferences and priorities. This is how you come up with the best decision for your situation.

This issue of Insights presents:

- A new tool that compares 28,000 peer reviewed papers to chart the effectiveness of different local treatments for each risk level.
- A New York Times bestselling author and friend of PCRI sharing his patient perspective, boiled down into 8 key points.
- A quick recap of the PCRI conference
- An introduction to a genomic test can add additional clinical perspective for men considering adjuvant or salvage radiation.

Everything that you learn about prostate cancer fits somewhere in the context of your own journey. The more you explore, the more you get a sense of where everything is relative to you. As you read this issue, we trust you are already on the path, aspiring to get the best care you possibly can.

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Fred Owen, Prostate Cancer Treatment Research Foundation, Executive Director

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Using Genomics to "Moneyball" Prostate Cancer

Sarah Neumann, BSc, Digital Development Manager, GenomeDx Biosciences

Elai Davicioni, Ph.D., President & CSO, GenomeDx Biosciences

Management of prostate cancer after surgery – the role of a new genomic prognostic tool that can "Moneyball" this complex disease.

A NEW ONLINE RESOURCE

Using information from 28,000 peer reviewed papers, the *Prostate Cancer Treatment Research Foundation*, in tandem with 28 medical experts, has created an online resource for men with newly-diagnosed disease that compares cancer control rates of various treatments.

*Fred Owen, PCTRF
Executive Director*

Men and their loved ones facing a decision about initial treatment can now access the results of an important, ongoing study showing how different treatments compare in their ability to eradicate prostate cancer, and prevent recurrence. The study is produced and continuously updated by the Prostate Cancer Results Study Group, a group of 28 medical experts in the field of prostate cancer diagnosis and treatment.

Because there are no randomized, controlled studies of initial treatments, nor will there be (no one would realistically submit to having a treatment, or placebo, chosen for them at random) this study took a different approach: Establish simple criteria defining "successful treatment" and chart the comparative outcomes of the different treatments.

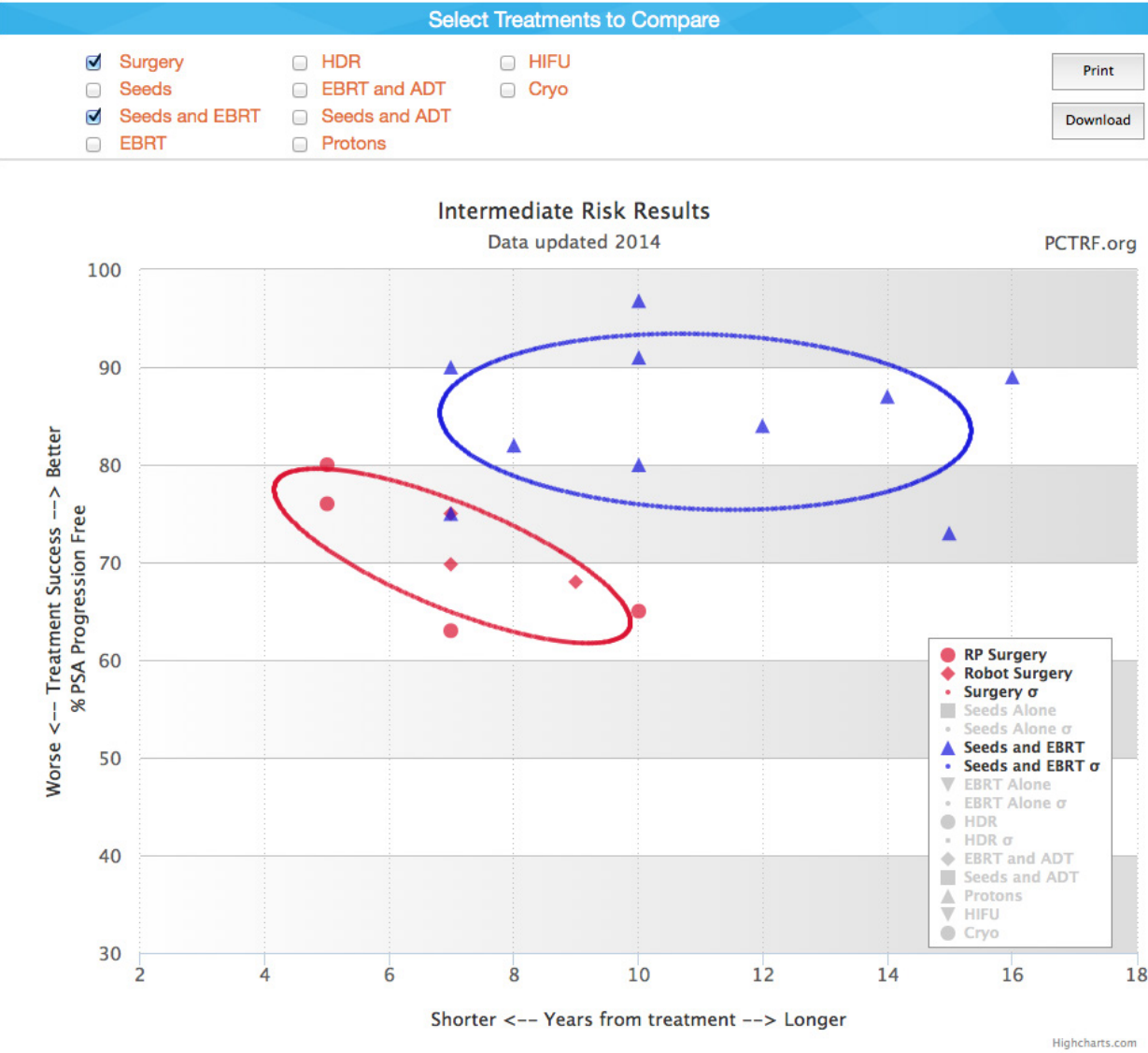
This elite group went to work, evaluating 28,000 published, peer-reviewed papers looking for ones that report recurrence based on rising PSA levels following primary treatment. To date, over 1,100 individual papers have been included in our project.

The study group learned the good news early; survival was good for most patients and for most

stages. However the cancer-control rates were often remarkably different between treatments. How did we determine the difference in cancer-control rates? We monitored the PSA levels. If the PSA increased after treatment, it means that another treatment was necessary. The study group's choice to analyze PSA recurrence rather than survival was deliberate; cancer recurrence based on a rising PSA will not only affect survival, it will significantly impact a patient's quality of life, not to mention the costs of treatment for advanced prostate cancer.

How does a patient, or loved-one, go about comparing these treatment results?

The results are published on the website of the Prostate Cancer Treatment Research Foundation (www.pctrf.org), an independent, non-profit, patient-supported foundation dedicated to patient education. The website has resources to guide a patient or caregiver through the process of determining their risk category, and leading →



Lessons I Learned along the Way

Ivan Misner, Ph.D.

Being a patient is not a passive role. For better care, a patient has to find quality professionals and collaborate with them. Ivan Misner, Ph.D., a friend of the PCRI and New York Times bestselling author shares his experience as a prostate cancer patient and shares a few important points he learned along the way.

The study mentioned in this article, the list of experts on the panel, and charts comparing more local treatments can be found at www.PCTRF.org

them to an interactive charting page that allows them to easily compare how different treatments affect cure rates. These comparative charts can be downloaded or printed to make it easy to discuss the options with family members and physicians.

In some cases, the differences in treatment results are dramatic. For example, in the intermediate risk category, the combination of brachytherapy and external radiation shows a control rate of about 85% going out 15 years, while the cancer-control rate for radical prostatectomy is about 70% going out only 7 years, with no data points beyond 10 years

(see the figure above). It is important to remember that in the realm of published medical papers, all reporting is voluntary so missing results can be informative as well; no one wants to publish results that are disappointing.

This tool provides a unique resource to help patients answer a very important question:

"What treatment will give me the best chance of making this cancer go away, and never come back?" □

Since my own prostate cancer diagnosis, I have had the chance to speak to several men immediately after they have heard the same words from their urologist that I heard in March 2012. I hope my experience and the many things I learned along the way can be helpful to you or someone you love who is starting out on this journey.

Please understand that I'm writing this from a patient's perspective. I am not a medical doctor. I am not giving you advice or addressing your particular situation. You must do your research, and consult with your doctor before making any decisions about what is best for you!

Right after I received my diagnosis, I spoke to five men and came away from these conversations knowing five ways I did NOT want to approach my own situation. But the conversations I had with all of them were invaluable. They also put the fear of God in me because of the side effects they told me about. I found the motivation I needed to put into effect the total and complete dietary and lifestyle changes I made.

Not long after receiving my diagnosis, I attended the Prostate Cancer Research Institute's annual conference in Los Angeles. I learned so much there from doctors who are at the cutting edge (no pun intended) of the emerging trends in prostate cancer diagnosis and treatment.→

The Top 8 Lessons I Learned:

1 Your PSA doubling time is important. Many times the PSA (a blood test which measures Prostate Specific Antigen) can begin to rise one or two points over a period of time due to age or other factors, but your PSA doubling time is more important when cancer is suspected by your clinician. I found it helpful to keep a graph chart of my PSA tests, so that I could really keep an eye on the amount of time it was taking for the count to rise. In my case, my PSA had not even doubled in any one year when my doctor said he wanted to take a look at why my number was going up. He went through the order of screening and diagnostic tests mentioned below. And, of special importance to me, when I made dietary changes after my diagnosis, the slowly rising number stopped and actually began to drop.

2 There are many types of screening and diagnostic tests you can do, ranging from less invasive to more invasive. For example, going from an elevated PSA to a biopsy may be going a bit too far, too fast, unless you and your doctor have other reasons for concern. There are many things which can cause a PSA test to come back elevated: bicycle riding, having used the hot tub prior to having your blood drawn, intimacy prior to the test, or prostate infection (prostatitis). I am surprised that most of the men I have talked to have not been made aware of these factors which could be the cause of elevated PSA results.

Remember, this is your experience. You have the right to request the types of tests you wish to have performed. If you feel your doctor is rushing from a slightly elevated PSA to a biopsy, do your own research, ask your own questions, and consider a second opinion.

One of the first things my general practitioner did after my annual PSA came back slightly higher than the prior year's test was to run the test again. When that one was also elevated, he recommended a course of antibiotics to rule out a prostate infection (prostatitis). When my PSA remained elevated, he then began to move into the following cancer-diagnostic procedures. He did a digital exam and then referred me to my urologist for an ultrasound.

3 A high-definition, color Doppler ultrasound or a multi-parametric MRI (mp-MRI) can be the next diagnostic step to take if the digital exam reveals an abnormality in the prostate gland. The ultrasound I had revealed the lesion. A high-definition, color Doppler ultrasound or an mp-MRI is especially important when you are doing active surveillance (point eight below).

Proper imaging can help you and your doctor tell when the tumor is preparing to grow or is actively growing. Angiogenesis, or excess blood flow, can increase to the lesion as the cancer cells begin to move into a more active phase. If there is no angiogenesis present, active surveillance may be one of your options. Color Doppler ultrasound is designed to show this blood flow. A mp-MRI can help detect this as well,

4 A PCA3 test can help give an indication of the presence of prostate cancer. The PCA3 test is a urine test that measures the prostate cancer gene 3. My first PCA3 result was after my diagnosis, and came in at 26 (my urologist estimates that it would have been just under 50 at the time of my biopsy), while subsequent tests have been 17 and now 13, considered negative for cancer. Numbers below 25 are considered "negative" and those above 25 are "positive."



Ivan Misner, Ph.D. is a New York Times bestselling author. He is the Founder and Chairman of BNI (www.BNI.com), the world's largest business networking organization. His book, Networking Like a Pro, can be viewed at www.IvanMisner.com. Dr. Misner is also the Sr. Partner for the Referral Institute (www.ReferralInstitute.com), an international referral training company.

5 Regarding your scans and other tests, request copies of everything, including written reports. Most of your doctors will be glad to make copies of the reports and even the imaging scans. I started a notebook in which I put my PSA graph chart, all my PSA blood test results, the ultrasound imaging reports and the biopsy results (pathology) report. Having this notebook gave me valuable information to keep a handle on where I was in the process, and it also was extremely helpful to the members of my medical team. Overall, it kept me in the position of captain of my "game."

If you ask for the imaging scans: the DVD you will get has an embedded program you need to install before you can open the images. Most doctors already have this program on their computers, whereas I did not. It took a few tries to view my scans before I realized I needed to install the program! Ask the radiologist about this before taking your DVD. You can also ask for copies of the written report.

6 Be aware of the after effects of a biopsy. Since there are bundles of nerve fibers encasing the prostate gland, the biopsy needle can nick them and cause temporary to permanent side effects, such as incontinence and impotence. These nerves can regenerate but it is a very delicate procedure. Please be sure you go to someone who has done hundreds and hundreds of these procedures. You don't want to be part of a learning curve for the new guy! After the biopsy you may urinate and ejaculate blood for a time. That can be painful, not to mention completely unsettling, even when you are aware it will happen.

If your biopsy returns positive for cancer, find out how many core samples were taken and how many of them were positive for cancer. This will be on your pathology report. This information will help you determine your risk category. PCRI has a great website into which you can plug all these factors to learn your "SHADE" on the risk spectrum. This tool can be found on their Blue Community website: www.pcricb.org

7 Another piece of information to come away from your diagnosis with is your Gleason score. This score is made up of two numbers called "Gleason grades". Adding the two numbers together gives you your score, but the order in which the numbers are added gives you information, too. If the lower number is given first, then the higher number (for example, 3+4), your risk is somewhat lower. If the higher number is first, then the lower (4+3), your risk is higher, even though both scores are a 7 on the Gleason scale. $3 + 3 = 6$ is the lowest risk, and $5 + 5 = 10$ is the highest.

Knowing my risk category helped me decide how I wanted to approach my treatment. My numbers all placed me in the low to intermediate risk category. Having all the diagnostic information I had helped me determine what I was going to do. It wasn't a case of the doctor diagnosing cancer and scheduling me for surgery a few months later! →

Thank You for Making The 2014 Conference A Success!



CONFERENCE RECAP

Peter Scholz, Communications Manager & Insights Editor

Thankfully we are at a point where rapid and significant advances in prostate cancer care are coming to light at a faster pace. Keeping up to date and learning about these new developments can maximize curative potential of your treatment plan and preserve quality of life in a way that wasn't possible a few years ago. The conference generated a lot of awareness and excitement for new developments in care across all spectrums of the disease. One consistent thing about the conference, is the constant stream of new information we get from the doctors who are on the leading edge of prostate cancer research.

Here at PCRI, we are excited that advancements in care are being made at every level, from Sky to Royal, both in technology and methodology. New research is allowing doctors to combine treatments in ways that weren't previously done, and to use new imaging technology to help choose the right treatment type and intensity.

On one hand, advancement in MRI technology is allowing for better active surveillance, and Dr. Robert Princenthal of Rolling

Oaks Radiology gave a presentation on Friday about how the technology is used. Advancement in MRI technology allows for less invasive active surveillance plans that keep track of the cancer more effectively. Dr. Eugene Kwon of the Mayo Clinic, said in his talk, "sometimes we need to go for curative outcomes, moreso than palliative ones if we have the capability of doing so." He discussed at length how a powerful new imaging technology, the PET Choline scan, helps when pursuing curative treatment for early-stage Royal (oligometastatic) cancer. Depending on where the metastases were found, a tailored multimodal treatment plan could be selected to maximize curative potential. At the conference, a survival study in men with advanced disease was presented comparing Lupron alone (standard care) versus Lupron plus Taxotere demonstrating that longevity was 17 months better for men receiving the combination. Dr. Maha Hussein and Dr. Snuffy Myers covered the exciting new study.

The PCRI Conference stays on the cutting edge of prostate cancer care, covering new information the moment that it becomes available and relevant. This information and more will be on the 2014 Conference DVDs. **Reserve yours today at www.PCRI.org or by calling us at 310.743.2116.** □



Speaker Q&A

In addition to the *general sessions*, patients and caregivers attended intimate *support groups*, interactive *Q & A's*, *discussion panels* & "*ask the experts*" sessions.



Support Groups

2014
PROSTATE
CANCER
CONFERENCE

2014 HARRY PINCHOT AWARDS

By Jan Manarite & Bill Manning

Every year at the Prostate Cancer Conference the PCRI presents the Harry Pinchot Award to advocate that exemplifies the same tireless advocacy and patient support Harry Pinchot was known for. This year there were two! Joel Nowak (left) and Gene Van Vleet (right).



Joel Nowak has fought thyroid cancer, prostate cancer, kidney cancer, and melanoma. In each situation, involvement in his own treatment made a significant difference in the outcome of the disease. Joel understands patient empowerment at a very personal level and has volunteered hundreds upon hundreds of hours helping men with advanced prostate cancer do the same. He has always been dependable for productive idea-sharing, honest feedback, and showed a willingness to step up, step back, or step any direction that helped to create solutions for prostate cancer patients. This is great advocacy, something Harry Pinchot always worked towards.

Joel writes a blog, which can be found at www.advancedprostatecancer.net where patients and caregivers can also post and interact with each other. Joel also works to further support for cancer research, for education, and for survivors. His activities have included providing testimony for government agencies, reviewing grant applications, running both live and internet support groups, speaking at cancer related conferences, health fairs, writing, and even meeting face to face with diagnosed cancer patients to help them navigate their realities. Of special note, Joel has led the advanced prostate cancer support group at the PCRI Conference for the past several years. His room is always packed.

Gene van Vleet's drive to learn about his disease, propelled him on a path involving a considerable amount of research. Gene works tirelessly for the Informed Prostate Cancer Support Group (IPCSG), at meetings, at home, on the phone, and developing a newsletter. Even while hospitalized, he was still taking calls and helping men with their cancer. His compassion and extensive knowledge allow him not only relate to other men, but to speak to their situation with authority, helping them navigate the endlessly changing waters of prostate cancer and its treatment. He has worked hard to fill the information gap pointing men in the right direction. And all of this is with a smile on his face!

Whether it's answering calls from across the country on the group's hotline, arranging speakers for monthly meetings, writing a newsletter, working as IPCSG COO, doing community outreach, or spending countless hours helping men navigate the labyrinth of treatments and information, it would be difficult to think of anyone more deserving of the 2014 Henry Pinchot award.

Congratulations to these amazing men, Joel and Gene, for winning the 2014 Harry Pinchot Award!

PROSTATE CANCER RESEARCH INSTITUTE



Helping men know their options

PCRI has exciting news!

We have been blessed with a **\$500,000 matching gift program** that matches dollar for dollar all donations designated for the "Imaging Awareness Campaign."

This campaign aims to bring awareness to the fact that a million men every year undergo random needle biopsy of the prostate when imaging with noninvasive **multi-parametric MRI** is just as accurate. We need to spread this news! A short video on our website: www.PCRI.org explains how millions of men who undergo PSA screening can be saved from invasive and unnecessary 12-core random needle biopsies.

This January we will complete our 18th year of service to patients with prostate cancer. While it's good to see how treatments have improved over the years, it's sad that treatment selection still remains industry driven. Rather than men getting treatment that is personalized to their individual need, they too often are herded into "standard industry fare."

PCRI provides non-biased educational resources for all stages of disease:

- Trained Helpline facilitators are only a phone call away.
- The Blue Community and our 1100 page website provide excellent resources.
- The SHADES of Blue help connect men with information applicable to their specific situation.
- Our annual conference enables patients to converse with world renowned experts.
- Our free quarterly newsletter keeps everyone informed and connected with the latest developments throughout the year.

State-of-the-art information is a Godsend for men and their families who need answers.

PCRI's programs and initiatives are 100% funded through charitable donations. Together with our new matching gift program your donation will make an even bigger difference. Your generous contribution gives us the support we need to continue to provide these services to men worldwide.

Thank you for your consideration it is appreciated by us and all those whom we serve!

A handwritten signature in black ink, which appears to read "Mark Scholz".

Mark Scholz MD
Executive Director



Mark Scholz, MD,
Executive Director, PCRI
& Medical Director,
Prostate Oncology
Specialists

**To donate online go to
www.PCRI.org and click
on the **DONATE** button**



Patient PSA Tests Biopsy Risk Scans Treatment Learned Doctor Side Effects

Lesson I Learned, continued from pg. 9:

8 Consider active surveillance, if appropriate for your stage of prostate cancer. Urologists and oncologists used to refer to a time of “watchful waiting” related to prostate cancer. Watchful waiting is now being referred to by many doctors and patients as “active surveillance”, which has a slightly different definition. Think of the word active as being active in getting your tests, the color Doppler or mp-MRI scans, and active in keeping an eye on the situation so you know when it is the right time to intervene medically. Active surveillance gave me the time and the space to make the lifestyle changes I made to see if they would give my body what it needed to repair the damaged cells. I had monthly PSA tests, regular HD color Doppler ultrasounds and saw my urologist every six to nine months to evaluate all my numbers. Even now that I’ve been told I am in remission, I will continue active surveillance.

I learned that a radical prostatectomy was NOT my option if at all possible! The side effects are common and often permanent. If I had a fast-growing malignancy, I might have responded differently.

I recommend a couple of books to read if you have been diagnosed with prostate cancer. The first is Invasion of the Prostate Snatchers, written by Dr. Mark Scholz, the founder of the PCRI. He has co-authored this book with one of his patients, and I found it extremely informative and comforting. Dr. Scholz is an oncologist, not a urologist, so surgery is not his first reaction to a prostate cancer diagnosis, as it is for most urologists.

The second is Love, Medicine and Miracles by Dr. Bernie Siegel. This book reveals the incredible power the mind has over the medical conditions of our bodies. Since hearing those words in March 2012 – “you have cancer” – I have come to believe more deeply just how integrated our mind and bodies are when it comes to healing from conditions like cancer.

Remember that you are “the captain” of your experience as a patient. Knowledge gives you the opportunity to make choices. Get as much information from sources you trust, and then do what YOU feel is best for you. It is your diagnosis. Treatment protocols need to be your choices – not someone else’s. □



By Sarah Neumann & Elai Davicioni



Moneyball, by Michael Lewis, tells the true story of how Billy Beane, the general manager of baseball’s Oakland Athletics, forms a winning team by analyzing individual player’s statistics. Instead of investing in one or two of the most well known players in the league, he scans through them all, using advanced statistical algorithms to pick out the ones who are perfect for a certain spot on the roster, but who otherwise would never be picked. This is how a San Diego based company, GenomeDx Biosciences, uses its Decipher platform to look at the genes in the genome. →

Where to get more information:

Web: www.deciphertest.com

Email: client.service@genomedx.com

Phone: 1-888-792-1601

Corresponding author contact: sarah@genomedx.com

WHO IT’S FOR:

Men at risk of prostate cancer metastasis after surgery.

WHAT IT DOES:

Predicts probability of metastasis:

5 yrs after radical prostatectomy (RP)³

& 3 years after a PSA rise after RP (Biochemical recurrence)⁴

THE TECHNOLOGY:

Microarray, which provides a read-out of over 1.4 million segments of expressed (activated) DNA from one archived tumor sample. Decipher reports on 22 of these expressed DNA segments.



Sarah received her BSc in Cell Biology and Genetics at the University of British Columbia, Canada, and spent four years working as a scientist and lab manager in the field of epigenetics before joining GenomeDx Biosciences.



Elai received his PhD in pathobiology from the University of Southern California and worked in oncology biomarkers at a computational biology company before launching GenomeDx Biosciences.

Genetic Profiling for Patients

The ability to collect over 1.4 million data points per patient tumor means that researchers are not restricted to the information provided by a few genes common to some cancer tests. Instead, Decipher is able to “moneyball” a winning team of cancer biomarkers customized for each clinical scenario. The Decipher test reports on the activity of 22 small sections of the human genome that are extracted from your prostate after it has been surgically removed. Analysis of these genetic sections provide a forecast of future risk of metastasis after radical prostatectomy.

If you are among the many men considering salvage radiation after surgery, the first thing that needs to be determined is the probability of the prostate cancer recurring. Genomic tests such as Decipher, help to provide a clearer picture.

Health care providers counseling patients in this situation face a dilemma. After surgery, they know that only 1 out of 10 men will develop distant metastasis without radiation treatment¹, but clinical practice guidelines recommend that all these patients be considered for radiotherapy². Risk factors like Gleason score, clinical stage and PSA do not provide doctors with an accurate enough prediction as to what may or may not happen with a patient’s cancer after RP. With this uncertainty, doctors tend to recommend radiation – not a pleasant undertaking for a patient on the road to recovery (e.g., from urinary incontinence and decline in sexual function) after surgery.

Genomic data can provide another layer of information that is independent from pathological analysis of cancer tissue. Pathologists examine sections of tissue under a microscope to assess certain factors such as the Gleason score and the status of surgical margins. In the genomics lab, the readout of DNA (gene expression, or RNA) from a small piece of tissue provides additional information.

The physician receives a report of the Decipher results in the same way that he would receive results from the pathology lab. A sample report can be found at www.PCRI.org.

Collecting “Stats” on Tumors

Genetic technology now available to health care providers allows them to collect and interpret genomic information to get a more accurate ‘biological read’ on a patient’s tumor and it’s future ability to grow and spread. Expression ‘profiling’ technology takes a snapshot of the activity of all of the genes in the genome from just a tiny sample of tumor tissue removed by RP. Cloud computing and advanced data analytics allow researchers to gather, store and rapidly analyze patterns for an individual patient which can finely characterize the biology of the tumor inside. The combination of millions of data points and the high-performance computing means that researchers can use algorithms to “Moneyball” prostate cancer to create accurate, clinically predictive tests.

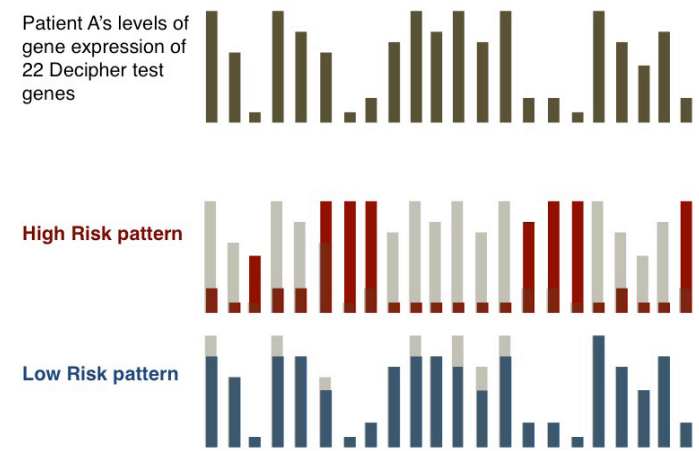
A simplified schematic of what it means to use gene activity (measurement represented by vertical bars) to predict metastatic risk is depicted in Figure 1. In this case, Patient A’s gene expression pattern more closely matches the pattern of gene expression for the average low risk patient studied. Patient A’s Decipher probability of developing metastasis might therefore be around 2%.



Validation by Scientific Studies

How do we know that these genes will actually predict relapse? The genetic markers discussed above have been scientifically validated.⁴ A study published by researchers at Thomas Jefferson University shows that when Decipher suggested a higher risk of future relapse, the patients who received immediate (‘adjuvant’) radiation had better outcomes.¹² Researchers also found that when Decipher indicated a lower risk of future relapse, delaying radiation did not compromise future cancer outcome.

Figure 1



Accurate Predictions Improve the Odds of Winning

What is important for patients and physicians making a clinical decision is whether their results indicate the presence of aggressive tumor cells that, given time, will spread, or if they indicate that the tumor has already been effectively cured with the surgery.

The test result from Decipher is presented in a report format that gives a prediction conveyed to you as a percentage risk of future relapse.

The Decipher Prostate Cancer Classifier is available to US patients through their physicians and as part of GenomeDx’s ongoing program of clinical studies. It has been validated to predict metastasis in men at risk of prostate cancer recurrence after surgery. □

By running the Decipher test on patients, information on the activity of 1.4 million gene segments within each sample of tumor is collected. If a patient consents to let academic researchers use their tumor’s gene activity data for further study it will be used to advance research on new drug targets and additional tests. This data may be used to help make future treatment decisions for the patient himself, or at least, it may benefit prostate cancer patients of the future - potentially his sons and grandsons.



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2015 Prostate Cancer
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