

In The

Know

Confronting Prostate Cancer

August 2013



It's In The Genes: An Interview With Dr. Matthew Cooperberg On The Decipher™ Prognostic Biomarker Test

by Virgil Simons

It is estimated that there are more than 920,000 cases of prostate cancer diagnosed each year world-wide with the highest age-standardized rates occurring in Denmark, Ireland, Australia, New Zealand, Belgium, France and the United States of America. Of this group probably at least 25% (more than 50,000 in the U.S.) will develop a recurrence following primary local treatment of surgery or radiation. From this group we can expect that 30% to 40% will have their disease progress to an advanced stage of therapeutic resistant metastatic disease.

But how do we know that “our” cancer is one that could progress. The answer is similar to what parents would tell each other in commenting on their children’s growth spurts, hair color, size, or weight: “It’s in the genes!” Recent research has shown us that much of how we define and treat cancer will be based on genetic determinants. To help us understand more of this new world of prognostic tools is Dr. Matthew Cooperberg, Associate Professor of Urology at the Helen Diller Family Comprehensive Cancer Center at the University of California San Francisco.

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EDITORIAL

Just saying.....

by Virgil Simons

In a time when the marketing of just about all products seeks to reduce us to the lowest common denominators to target their messages to the groups in which they place us, we are seeing an opposite trend - the personalization of therapy - in the diagnosis, treatment and management of prostate cancer.

Research has shown that prostate cancer is not a single disease, even within an individual. It will have the potential to change its microenvironment (the locations where it grows), its genetic signature, as well as its aggressiveness. We will see more offerings of diagnostic and prognostic tests, new biomarkers to measure potential for progressive disease, and the customization of treatment protocols.

The problem with all of this is that it will add significantly more structures of cost to a system already the most expensive in the world and one where the implementation of broader, if not universal, access is still being held hostage to political bombast and commercial self-interests. There is an ever increasing need for consumers and patients to become more aware and educated about the system and their options for achieving the best standard of care and desired quality of life.



SPOTLIGHT ON: Neuroendocrine Prostate Cancer— with Dr. Kenneth Pienta

By Diane Johnson

JULY, 2013

I recently spoke with Kenneth Pienta, MD, Professor of Urology, Oncology, Pharmacology and Molecular Sciences at the Johns Hopkins University School of Medicine, about an evolving form of prostate cancer—neuroendocrine prostate cancer. Dr. Pienta first identified the problem in a presentation at this year's ASCO-GU symposium.



Kenneth Pienta, MD

DJ: Thank you for taking the time to speak with us, Dr. Pienta. To get started, what are neuroendocrine tumors and how do they relate to prostate cancer?

KP: Historically, these tumors have been referred to in several ways—neuroendocrine, small cell, or anaplastic. Essentially all of these terms refer to cells that do not have or have very low amounts of androgen receptor—cells that do not respond to testosterone. Classically, these are a very small percent of newly diagnosed metastatic prostate cancer. This type of cell doesn't make much PSA or have much androgen receptor, but does have some markers of neuroendocrine cells like neurohormone-type receptors.

DJ: Is this a new type of prostate cancer? If so, why is it happening now?

KP: It is not a new type of prostate cancer, but we are now seeing more patients with it. Now that we have such effective new hormonal therapies in the form of not only LHRH agonists, but also drugs like abiraterone (Zytiga) and enzalutamide (Xtandi), we are helping people live longer and

The Prostate Net



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African-American Men and Abiraterone: Does Race Matter?

By Virgil Simons

African American men have a higher incidence of prostate cancer, and present with more advanced disease, compared with Caucasian men, in the United States. In addition, African American men have a higher likelihood of dying of prostate cancer. While several factors likely account for these disparities, difference in the production and metabolism of male hormones (for example, testosterone) may play a role. These differences could also theoretically impact the way in which African American men with advanced prostate cancer respond to treatment.

Abiraterone acetate is a “hormonal” therapy for men with advanced prostate cancer that has been demonstrated in large clinical trials to extend patient survival. Unfortunately, like most clinical trials, a very small proportion of men enrolled in the clinical trial were African American, raising questions about whether the findings are truly clinically relevant to a population of African American men with prostate cancer.

In an attempt to demonstrate that Abiraterone acetate also works in African American men with prostate cancer, and to determine whether genes involved in the metabolism of male hormones impact the response to treatment, Dr. Matthew Galsky of Mount Sinai Cancer Center (NY, NY) has initiated, to his knowledge, the first clinical trial specifically evaluating a medication for advanced prostate cancer in African American men: A Pilot Study of Abiraterone Acetate in African American Patients With Castration Resistant Prostate Cancer.

To provide some perspective and information on the study, we’re speaking with Dr. Matthew Galsky:

VHS: It has been shown that African-American men have certain genetic areas, e.g. 8q24, that are more highly expressed in Pca than other groups. Will your study use any genetic testing to identify the presence of these markers in the potential participants?

MG: Yes, although the sample size is small for robust observations, each man will have a blood sample drawn at baseline for germline polymorphisms in androgen metabolism genes and these will be correlated with “response” to abiraterone (post-treatment decline in PSA).

VHS: We have seen that the use of AR-targeted drugs has had a correlation with subsequent manifestation of neuroendocrine Pca. Do you foresee a disproportionate incidence among African-American men in the study?

MG: This is a very good, and complex, question. Whether these drugs are altering the natural history of the disease in a

meaningful way as to “create” neuroendocrine PCa, versus whether patients are living longer as a result of these therapies such that new resistance mechanisms are emerging (similar to the increase in brain metastases observed after herceptin was introduced for breast cancer — it is unlikely that herceptin causes breast cancer but rather that disease outside of the central nervous system



Dr. Matthew Galsky

was controlled that much better allowing brain metastases to emerge) is not clear to me at this point. If this phenomenon is occurring, whether it is more likely in African-American patients is a very interesting, and as yet unanswered, question. Although the sample size is small, given the prospective nature of this study, we will certainly be able to track this to the extent that we will have detailed information on sites of progression and whether or not PSA is rising at the time of progression.

VHS: Will the study evaluate abiraterone versus another agent or versus placebo?

MG: All patients in this study will receive abiraterone, in a Phase II-like design.

VHS: What will be the trial protocol (length of study, number of treatments administered, monitoring plan, patient costs, etc.)?

MG: Patients will continue abiraterone as long as they are benefitting and not experiencing treatment-limiting side effects. The visits are roughly once per month. The abiraterone is provided free of charge. The procedures that would be done as “standard of care” (e.g. physician visits, routine labs, etc.) are billed to insurance as is standard for clinical trials. Any procedures that are strictly for research purposes (e.g., gene polymorphisms) are paid for by the study.

VHS: What will be the evaluated outcomes of the study?

MG: The primary outcome measure is the proportion of patients to achieve a post-treatment decline in PSA. We recognize the limitations of PSA as an outcome measure but in a small study of this type, this should provide as adequate

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Neuroendocrine Prostate Cancer

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longer with metastatic disease. But as we knock out the AR positive cells, we are seeing the emergence of this anaplastic prostate cancer that is very difficult to treat. It used to be seen only in a small percent of people, because the AR positive cells were the vast majority. Now that we've killed those cells off, neuroendocrine cells are growing up and becoming cells that will kill men with metastatic disease in the long term. Because we have such great drugs to help guys live so much longer with metastatic disease, a new cancer is evolving in response to these good drugs.

Most of us agree that there are several different cell types that are emerging in post-abiraterone, post-enzalutamide patients. Pathologists are trying to define exactly what a neuroendocrine cell is. Over the next few years we will be classifying the cells into broad categories. For example, there are cells that are neuroendocrine, with the neurohormonal markers and there are other cells that are very anaplastic, very de-differentiated, and do not have these markers. Then there are cells that do not fit these two categories that may be driven by specific growth factors.

DJ: Where are these tumors found? Are there symptoms to watch for?

KP: Neuroendocrine prostate tumors are found in the same places that androgen receptor positive cancer cells are found--in bone and many different organs. 10 years ago, when somebody died of prostate cancer, you mostly found prostate cancer in the bone. But now, as we've become more effective at helping men live longer, we've begun to see much more disease in soft tissues too—for example, the liver, the lungs, the adrenal glands. Another place where we've begun to see more disease is in the lining of the brain called the dura. Back when we started doing autopsies on men with prostate cancer, 40% of the men had prostate cancer on the dura, but it was asymptomatic. Now, as men live longer, we are seeing more and more of them becoming symptomatic. They could have cranial nerve palsy or a facial droop could develop. Because this is near the brain, we think it might be that these metastases are of the neuroendocrine

phenotype, but it could be unrelated. We just don't know yet.

From a symptom standpoint, these men don't necessarily have new symptoms; they tend to have more disease with less PSA than they used to. Cells [from a biopsy of a] metastatic tumor would show more of the anaplastic or neuroendocrine phenotype, rather than the AR positive and more differentiated kinds of cells we used to see. But we do not see different symptoms due to the phenotype of these cells.

DJ: How is neuroendocrine prostate cancer treated?

KP: We are actively trying to develop new treatment regimens for this type of cancer. Part of that is going to be establishing the different types of cancer. This is where personalized medicine may become important in identifying what mutations these anaplastic tumors have. For example, are they driven by growth factors, such as fibroblast growth factor or epidermal growth factor, by androgens or by neurohormones? That will change how we treat them. As we biopsy and sequence more men, we will learn what mutations they have, so we can put them on specific therapies for their specific mutation.

In the meantime, platinum-based regimens are the chemotherapies of choice for these types of tumors. For example, Drs. Logothetis and Corn, at MD Anderson, are treating this anaplastic subgroup of tumors now with a clinical trial that combines cabazitaxel and carboplatin. We do see responses with it, even more responses than we used to.

We still have to define this new type of prostate cancer much better.

Editor's note:

A video of Dr. Pienta discussing this issue can be seen at: http://www.oncologytube.com/index.php?page=videos§ion=view&vid_id=1031557

For more information on the MD Anderson trial, go to www.clinicaltrials.gov and search for trial # **NCT01505868**.

It's In The Genes: An Interview With Dr. Matthew Cooperberg On The Decipher™ Prognostic Biomarker Test

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Dr. Cooperberg, I think that it's important to define what is "advanced stage prostate cancer" because we've heard it referred to patients in primary therapeutic failure, those who have failed hormonal therapy, those who've failed chemotherapy, and those showing resistance to metastatic disease treatments.

MC: "Advanced stage" is a term used differently by different people, but generally speaking it implies metastasis: cancer that has spread to lymph nodes and/or to the bones—or at least a cancer that is well outside the prostate (i.e., into the seminal vesicles). In the era of PSA-based screening, we have substantially reduced the incidence of advanced stage and lethal prostate cancer, but unfortunately many men still either are never screened or have cancers that are found too late and ultimately progress. As you said, in such cases the cancers tend to recur after primary treatment and ultimately need hormonal therapy, chemotherapy, etc. There has been an explosion of new therapies to help men with advanced stage prostate cancer, but unfortunately none of them is curative, and the best chance at curing high-risk prostate cancer remains surgery and/or radiation therapy when the cancer is confined to the prostate or the area immediately around.

VHS: Thank you for that; but we want to get to heart of this new clinical era of genetic modeling and personalized medicine. What do we know about the genes related to prostate cancer and how will they change the way the disease is treated?

MC: The sheer volume of data, which has been gathered about cancer genetics in recent years, is absolutely staggering, and our knowledge base and understanding of genetic regulation of disease progression is growing by leaps and bounds. However, a great deal of what we have learned is just how much we still don't know. Specifically, the regulation of DNA transcription to RNA and RNA translation to protein turns out to be much more complicated than we once recognized, and indeed, microRNAs and other non-translated RNAs which comprise some of the most promising biomarkers around today were all basically unknown a decade or so ago as genetic "dark matter." Now, however, it is easier than ever before to identify consistent patterns in gene expression that help us make more accurate predictions about cancer behavior. By looking for genetic signatures of high- and low-risk tumors, our hope is to identify high-risk cancers early and treat them aggressively, while avoiding unnecessary treatment for lower risk tumors that are unlikely to progress.

VHS: Up until this point, the two key determinants of potential aggressiveness or recurrence were positive (or negative) surgical margins and the PSA level and velocity. What can



Dr. Matthew Cooperberg



genetic markers tell us that the current standards can't?

MC: Margins, pretreatment PSA, the cancer grade (Gleason score), and extent of spread (stage) are all important prognostic factors with respect to tumor behavior. These factors can be combined to make predictions with 75 to 80% accuracy, so the bar is actually fairly high for genetic

markers to improve these predictions. However, we are now seeing development and validation of markers that can in fact do just that: help us improve on the current clinical state-of-the-art.

VHS: One of these new prognostic genetic biomarkers is the "Decipher™ Prostate Cancer Classifier". Some of your research studies have shown a high degree of significance for this test. Would you please explain what it is and its importance for patients and physicians.

MC: Decipher is one of a number of tests now reaching the clinical marketplace that are based on measuring expression of sets of genes. Decipher focuses specifically on high-risk prostate cancer and questions about multimodal therapy—in other words which patients may benefit most from a combination of surgery, radiation therapy, and/or systemic therapy. Like other, similar tests, Decipher is a score derived from expression levels of a set of defined genes: in this case, 22 genes. However, Decipher is unique in that beyond the 22 genes which contribute to the score, over 1 million sequences, or markers of gene activity, are actually measured on each cancer analyzed, which creates a future opportunity to refine the score and make other projections about responses to future treatments as our knowledge base continues to improve.

VHS: What kind of conversation should a patient have with his doctor regarding Decipher™: when should it be used; what kind of information will it determine; what action should or not be taken based on the results?

MC: At this point, Decipher has only been clinically validated for men who have already had surgery, and are trying to make decisions about whether to follow up with radiation therapy, hormonal therapy, or other treatments. I hope that in the near future, the test will also be available to run on biopsy tissue for men who have not yet had treatment and are deciding which initial treatment(s) to pursue. The test does not give a binary readout—in other words it does not translate to a yes/no decision about further treatment; no test currently available or in the near-term pipeline can do that.

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ASCO 2013 SHORTS

By Diane Johnson

JULY, 2013

FIGHT CANCER WITH FITNESS

(Cooper Center, Dallas, TX, Lakoski et al)

Over 17,000 middle aged men were given a preventative health exam that included a cardiorespiratory fitness assessment, and then divided into five groups by fitness level. The study tracked them for 20 years during which 2885 men were diagnosed with prostate (2332 men), lung (277 men) or colorectal (276 men) cancer. The study found that men who were more physically fit at middle age were less likely to be diagnosed with cancer and, if they did develop cancer, more likely to survive it. Men who were less physically fit, but not obese, still had a higher risk of cancer and cardiovascular disease. The lead author, Dr. Susan Lakoski, University of Vermont, said, "This is the first study to explore fitness as a marker of cancer risk in men and a marker of prognosis after a cancer diagnosis." She also noted that "... fitness is your ability to be efficient at getting oxygen to all of your organs. [That] is very important in modulating different pathways involved in inflammation, hormone levels, immune surveillance, oxidative damage. All of these things play into reducing cancer risk. The message is: Be Fit."

[Abstract #1520

<http://meetinglibrary.asco.org/content/111825-132>]

SULFORAPHANE TREATMENT IN MEN WITH RECURRENT PROSTATE CANCER

(Knight Cancer Institute, Oregon Health & Science University, Joshi J. Alumkal et al)

In a small study, men with recurrent prostate cancer were given 200 umol a day of sulforaphane, a substance found in cruciferous vegetables like broccoli whose high consumption is associated with lower prostate cancer risk. 200 umol per day is roughly equivalent to three servings of cruciferous vegetables. The primary endpoint of this study was PSA response (>50% decline). After 20 weeks, one patient had a greater than 50% PSA decline and approximately half of the men had some decline in PSA. PSA doubling time was also affected—from 6 months before the study to 9.4 months during the study. Dr. Alumkal, lead author, said, "Our trial demonstrates the safety of sulforaphane and that the rate of PSA rise in many patients was slowed. Our [next] goal is to partner with a company that has a pharmaceutical version of sulforaphane and to perform dose escalation studies that include measurements of sulforaphane's effect in tumor tissues."

[Abstract #5017

<http://meetinglibrary.asco.org/content/115604-132>]



RADIUM-223 (XOFIGO)

Radium-223 was approved in May by the FDA. This injectable drug, delivers targeted radiation that kills cancer cells in the bone. At the ASCO Annual Meeting, a poster was presented showing a study of men with advanced prostate cancer who were treated with Radium-223. They found that the drug "significantly prolonged overall survival and had a highly favorable safety profile" in men with hormone-resistant prostate cancer who had bone metastases, whether they had previously received docetaxel or not.

[Abstract #5068

<http://meetinglibrary.asco.org/content/114175-132>]

UPDATE: Another Radium-223 based study was published in The New England Journal of Medicine in July. A group of over 900 men with very advanced prostate cancer showed a 30% improvement in median survival time, from 11 to about 15 months. They also had fewer side effects like bone pain and muscle weakness. Dr. Chris Parker, Royal Marsden Hospital, London, lead author of the study, said, "If the drug were used earlier and the 30% benefit maintained, it would give a longer absolute benefit." Radium-223 is also being studied as a treatment for bone metastases in other cancers.

[Abstract #5068

<http://www.nejm.org/doi/full/10.1056/NEJMoa1213755>]

LIFE AWARD GIVEN TO DR. SIRAJI OBOYO, UGANDA

ASCO's Conquer Cancer Foundation awarded the 2013 LIFE Award to Dr. Siraji Obayo. Dr. Obayo, an oncologist at the Uganda Cancer Institute, received the award for his research into the development of a non-invasive prostate cancer biomarker. He received a one-year international fellowship to study and train in the U.S. "Prostate cancer is now the leading cancer diagnosis for African men, and it is on the rise," said Dr. Obayo. "We really need a mechanism that is quick and cheap to diagnose [the disease]."

A Choice for Life: Proton Beam Therapy

By Virgil Simons



Zelda and Victor Lawson

“You’ve got cancer”, like so many others those words put Victor and Zelda Lawson into a state of shock and started them down the path of discovery and choice on a life-or-death decision. While the likelihood in today’s world, that diagnosis isn’t an immediate reason to start making a will, it is a cause to question what your life will become trying to live with/survive cancer.

They went through all of the usual procedures: 2nd/3rd consultations, support group meetings, questioning friends, Internet searches and came down to the options of active surveillance, surgery or radiation. Victor is a man of action and the thought of just monitoring his cancer to see what might happen was not part of his nature. Likewise, the potential of incontinence and/or erectile dysfunction resulting from surgery was equally unappealing. Finally, they decided that radiation treatment would be the best option to cure his cancer. But, what kind?

There was brachytherapy (seed implants), external conformal beam (IMRT), or proton beam therapy. Seeds felt too invasive, almost like surgery. He knew about the National Cancer Institute report that said that there was no difference between IMRT and proton beam radiotherapy. But like other families in deciding on their decisive choice, data was not the paramount concern.

In comparing proton beam therapy to the genesis of robotic prostatectomy surgery, there were similar conditions: higher cost of acquisition by the medical centers, higher cost to the patients for the procedures, and questionable benefit in managing side effects and extending survival. In addition to the JNCI article noted above, Kaiser Health System produced a report that positioned the issue as one of marketing imperatives. Cancer Today magazine provided a

comprehensive look at the pros-and-cons of both IMRT and proton beam, could not conclude that one procedure was superior (or inferior) to the other, but made the important observation that, **“patients making treatment decisions may not view the data about side effects in the same way as a researcher. If you have prostate cancer, you might have a different perspective.”**

What are the facts that we know about the two:

- Proton beam radiation delivers high-energy beams precisely to a tumor, but only low doses to nearby tissue
- Conventional radiation delivers X-rays to a wider area including the tumor and adjacent tissue
- The incidence of urinary problems was lower for proton therapy at 6 months but virtually equal at 12 months
- A recent study done by MD Anderson and reported in the Wall Street Journal reported virtually the same urinary and bowel function for proton-treated men versus healthy, untreated men
- The cost for proton beam therapy is approximately twice that of conventional IMRT treatment

Given this lack of clinical certainty, then there is no doubt that decisions will be made from other criteria. With Zelda and Victor, those other factors were what lead them to the NJ ProCure Proton Therapy Center. Unlike many radiation centers that are housed in the basements of hospitals, the ProCure Center provided an open design, naturally sun-lit environment evocative of a family room on a grand scale, or a social club for you and your best friends. And it was this environment coupled with the collegiality of the staff and the on-going support from current and former patients that aided in making the decision. But it’s better if Zelda and Victor tell you themselves. We have a video of them providing their concerns, perspectives on the process, and outcomes.

A not unbiased comment comes from Leonard Arzt, Executive Director of the National Association for Proton Therapy, again as reported by the Wall Street Journal, “If the costs were the same, there would be no debate. Less radiation to healthy tissue is always better for the patient.” At the end of the day, choice, be it for surgery, radiation or anything else, will come down to the patient and family’s comfort level with how they want to live their lives.

For more information on proton beam therapy, you can contact New Jersey ProCure at:
<http://www.procure.com/OurLocations/NewJersey.aspx> or 1.877.967.7628

For more about Zelda and Victor’s story and info on proton therapy, visit:

http://theprostatenet.org/protonbeam_reflections.html



Building Global Alliances

The reality of prostate cancer is that it is truly a global disease, killing men at a comparable rate to that of the United States, and disrupting families and their plans for a full and complete life.

The Prostate Net has long had alliances across the globe: in Argentina partnering with medical professionals in developing patient educational tools, in India utilizing our Barbershop Initiative to promote prostate cancer awareness and tobacco cessation, Australia with the Prostate Cancer Foundation of Australia to promote disease education, and with the World Wide Prostate Cancer Coalition working to build patient advocate coalitions in Africa and the Caribbean.

Building on our experience, we have now developed a collaboration in Spain with the Fundacio-Puigvert, one of the foremost urological centers of excellence in Europe, FEFOC (Fundación para la Educación Pública y la Formación en Cáncer), the leading prostate cancer advocacy organization in Spain (and an Us Too chapter, as well as a member of Europa Uomo), to present a patient educational symposium on prostate cancer.

This will be the start of our coalition in Spain and the foundation for additional collaborations in Europe in partnership with key medical centers, patient advocate organizations and industry coming together to deliver services in support of the patient.

Information on the Symposium can be found at:
<http://theprostatenet.org/Symposium.html>

In the spirit of sharing common goals that will deliver educational and support services to patients and their



Dr. Jordi Estape

families, FEFOC and The Prostate Net are sponsoring “A Night of JAZZ Against Cancer” to generate funds that will enable FEFOC to carry on their mission that was started more than 16 years ago. We will together examine initiatives that have proven to be beneficial in other areas of the world and work to implement them in Spain. Again, future partnerships with other

advocacy organizations in Europe will be developed to expand mutually designed patient-centered objectives. Details on the “Night of JAZZ” can be viewed at:
<http://theprostatenet.org/jazz/index.html>

We welcome inquiries from interested groups into furthering collaborations. Contact us at: support@prostatenet.org.

African-American Men and Abiraterone: Does Race Matter? continued from page 3

signal that abiraterone is, or is not, associated with anticancer activity in population of African-American men with prostate cancer. Other outcome measures include safety and a correlation between genetic polymorphisms in androgen metabolism genes and “response” to abiraterone.

VHS: What are the clinical parameters for participation in the study?

MG: Patients need to have a history of castration-resistant metastatic prostate cancer that is progressing despite standard hormonal therapy (e.g., GnRH analog +/- bicalutamide). Patients may have received chemotherapy but they do not have to have received chemotherapy.

VHS: Does a potential participant need a referral from his doctor and will the doctor be kept informed of the patient’s status?

MG: A referral is not necessary. We will send copies of each study encounter to the patient’s primary oncologist and/or primary care physician.

VHS: If a patient is interested in participating in the study or wants more information, is there a number they can call or a website with details.

MG: Any interested patients can call my office for further details at: 212-824-8583



The Prostate Net **europa**



Fundació Puigvert

Cáncer de próstata: ¿convivir o tratar?

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Dr. E. Ruiz Castañé
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(Director del Servicio de Urología)



The Prostate Net **europa**

Programa

- 15.00 h : Bienvenida y presentación del programa
- 15.30 h : ¿Cuándo hacerme una analítica sanguínea por el PSA?
- 16.00 h : No tratar el cáncer de próstata, ¿es correcto?
- 16.30 h : Pausa café
- 17.00 h : Cáncer de próstata avanzado: cirugía, radioterapia o tratamiento hormonal
- 17.30 h : Nuevos tratamientos para el cáncer de próstata con metástasis
- 18.00 h : Vida sexual y cáncer de próstata
- 18.30 h : El papel de las asociaciones de soporte en cáncer
- 19.00 h : Estrés pre y post cirugía radical de próstata
- 19.30 h : Clausura

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93 416 97 32 y preguntar por la Sra. Lluïsa Ponsó.

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Cafe Vients
JAZZ CLUB by
Moët & Chandon

Premiere Season Charity Concert

TO BENEFIT PATIENT EDUCATION

A Night of Jazz Against Cancer

Date: 26 September, 2013
Time: 21:00 until 23:00
Location: Cafe Vients Jazz Club
Hotel Casa Fuster
Paseo de Gracia, 132
08008 Barcelona, Spain

Special Dinner Menu
Welcome champagne or cava drink
Selection of 5 hot and 5 cold tapas
Wine selection to accompany the tapas
Dessert
100 euros per/person
A portion is tax deductible (35 euros) as a charitable contribution

Featured performer:
The Steve de Sward Blues Trio

• Raffle prizes valued up to 100 euros (1 ticket included with each reservation; additional tickets may be bought on site for 5 euros each)
• Limited seating available; reserve your space online at: www.theprostatenet.org/Jazz
For more information, contact Guest Relations +34.932.533000 or email: support@prostatenet.org

FEFOC The Prostate Net **europa**

Charity benefit to increase disease education and patient support for those at risk of, or living with, prostate cancer



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However, it does give important additional information about the genetic aggressiveness of the cancer, which can help give some sense of whether a tumor after surgery is likely to need additional treatment.

VHS: In your opinion what are the characteristics of those patients who can most benefit from using the Decipher™ test?

MC: The answer to this question depends to an extent on one's perspective about the benefits of postoperative radiation therapy. There is clear evidence that for men with high-risk disease after surgery, adjuvant radiation given early is more effective than radiation given very late when the cancer is already progressing. However, whether there is a benefit for true adjuvant radiation—i.e., radiation given in the setting of an undetectable PSA—over early salvage radiation, given when the PSA is rising but still low, remains controversial. The other challenge is that the decision about radiation is really a three-way rather than two-way question: some men with relatively low risk don't need any treatment; others have very high-risk cancers, which are likely to have already spread at the microscopic level. Therefore it is men in the middle who are most likely to benefit, and we don't yet know exactly how to identify them. So at this point Decipher is likely best for men who are trying to make a decision about adjuvant radiation right after surgery, or perhaps those with

an early rising PSA, or those with a very low burden of lymph node disease. Certainly we are very excited about the prospect of using this test in the setting of clinical trials to identify men best suited for novel, emerging treatments. The truth is that it will take time, experience, and the collection of more data to figure out the optimal use for Decipher and other tests like it. We are far from the end of the story, and not even at the beginning of the end. We do stand, however, at the threshold of a new era in precision medicine in oncology, in which treatment decisions can be individualized, guided by detailed knowledge of an given tumor's specific genetic potential.

Thank you very much, Dr. Cooperberg, in helping to expand the spectrum of patient education and empowerment.

Editor's Note: For more information regarding Dr. Cooperberg, his clinical and research activities, see: <http://www.urology.ucsf.edu/people/matthew-r-cooperberg>

For more information on the "Decipher™ Prostate Cancer Classifier", visit the company's website at: www.genomedx.com. There is also Financial Assistance for those patients with insurance limitations through GenomeDx's "Patient First Program"; for information call: 1.888.792.1601.

For a video of Dr. Cooperberg discussing the situation of prognostic evaluation and the "Decipher™ Prostate Cancer Classifier", visit: http://www.oncologytube.com/index.php?page=videos§ion=view&vid_id=1032364

Leah's Story

By Leah Troiano

My story started when my 3-year-old child and 32-year-old husband were diagnosed with tumors in the same year. At first, we went through what everyone goes through, sadness, uncertainty and fear. With time we slowly adapted to living life with a cancer diagnosis and learned the importance of getting involved, taking control and never giving up.

To take an active role in my family's treatment, I decided to learn as much as possible. I became a Certified Cancer Educator, and worked one-on-one with patients who wanted to better manage their lives and diagnoses. This is when a colleague told me about StoreMyTumor and explained the importance of preserving and storing tumors, especially in a live format. She said that each tumor is unique, like a fingerprint, and that's why physicians research them. She added that having control over your tumor was essential. Years later, when my father ended up with a cancer diagnosis, I didn't hesitate to store his tumor.

Since each tumor is molecularly unique, the information the tumor holds can be used to test and target treatment. For example, therapeutic agent sensitivity testing uses live tumor to find the most effective cocktail of drugs to kill the tumor. This testing could help eliminate trial and error in



Leah Troiano

administering different treatments, avoid possible severe side effects, and aid in slowing disease progression. Using tumor tissue for genetic testing could help identify genetic mutations that are known to react effectively to a specific medical treatment. For example, several studies are underway looking at the response of androgen deprivation agents in prostate cancer. Immunotherapy also uses tumor tissue to create a vaccine that stimulates the immune system to attack and kill the tumor.

I wish I had known about tumor storage sooner. That's the comment I hear often when attending cancer conferences or providing patient education talks. Awareness is an issue and often patients learn about the importance of tumor tissue too late. Now, I do everything I can to spread the word, because when cancer advances, every option counts.

Leah Troiano is a patient navigator, certified cancer educator and a professional writer.

Editor's Note: For more information about tumor storage, visit www.storemytumor.com

Banking for the Future: Storing Tumor Tissue for Personalized Treatments

- By Virgil Simons

In this issue we've talked a bit about the concept of personalized therapy and new diagnostic/prognostic tests and the need for new biomarkers. We've explored the problem of drug resistant and cancer recurrence (or occurrence) of lethal cancers not killed by the targeted drug agent. But, as Bob Gillies and Bob Gatenby detailed in their article in this issue, true personalized medicine starts at the core with the analysis and therapeutic modeling proceeding from specific biological material of each person.

We've asked Dr. Miles Varn, Chief Medical Officer for PinnacleCare Private Health Advisory service, to put the subject into perspective for us.

Virgil Simons: Dr. Varn, why is there such a groundswell around the idea of "personalized medicine"?

Miles Varn: The basic problem is trying to fit the actual management of an individual patient into the framework of how medicine is actually practiced today. Therapeutic advances come from years of research ranging from basic lab sciences to clinical trials with Phase 1 through 3 evaluations and then publications of findings in various journals and concomitant clinical usage and review to establish a standard of practice. All of which is not necessarily relevant to a patient's treatment for cure or progression-free-survival.

VS: Dr. Robert Gatenby from Moffitt Cancer Institute believes that true personalized medicine must start with a patient's own genetics and not just a broad spectrum agent that may or may not have applicability in the specific situation. What is your take on this?

MV: He is correct in acknowledging that advanced molecular testing (genomic, proteomic, hormonal) must be utilized to look at each patient's data, analyzing the tumor and its mutations that will enable the creation of appropriate markers to determine 2nd line therapies, any subsequent resistance, and then recommendation for the correct 3rd line therapy based on that patient's own genetic manifestations. One important service emerging for patient usage within this context, that I've noted, is offered by StoreMyTumor.com, which helps a patient collect and save their own tumor tissue alive and for potential use in immunotherapy and targeted diagnostics such as chemo-sensitivity and genetic testing.



Dr. Miles Varn, Chief Medical Officer for PinnacleCare Private Health Advisory

VS: There has been mixed comment regarding this and similar services. In conversations with several pathologists and clinicians, there was support for the idea of a patient conserving their own tissue, but expressed problems in the present system accommodating the requirement. What is your perspective?

MV: Without question there is a need for original tissue (fresh, frozen and fixed) in downstream tumor

modeling, but there will be a challenge for the patients in obtaining their tissue from institutions that have their own research studies on-going and utilize acquired patient tissue for those studies. While many major institutions regularly store tissue samples, it is not standard for most community hospitals, and gaining release to the patient will be a problem.

There will probably be fights with the pathology departments in obtaining the tissue in the requested formats and having it properly handled. Patients will need legal, technical, storage and logistical expertise that they cannot coordinate on their own. The key problem is, that while many hospitals preserve tissue samples in paraffin, they don't normally retain them in formats of most potential benefit for patients, e.g. live for immunotherapy and chemo-sensitivity, frozen for genetic sequencing.

There will be a need to educate physicians, pathologists and institutions as to why the fresh tissue is needed and in how to process it straight from the operating room to the lab. And there will be questions as to price, though it should be compared with a chemo-sensitivity test for example in terms of processing effort, such procedures are not usually covered by insurance and must be paid by the patient.

VS: Thank you, Dr. Varn, for providing this commentary on an important patient-centric issue.

Editor's Note: For more information on Dr. Miles Varn, see his PinnacleCare Executive Team profile

For a discussion on Tumor Storage technology, see this article by Dr. Sue Criswell-Hudak

Visit www.StoreMyTumor.com for information on the services offered by this company.



The Commonwealth Fund Connection: Check Your State's Status and Potential Impact on the Uninsured

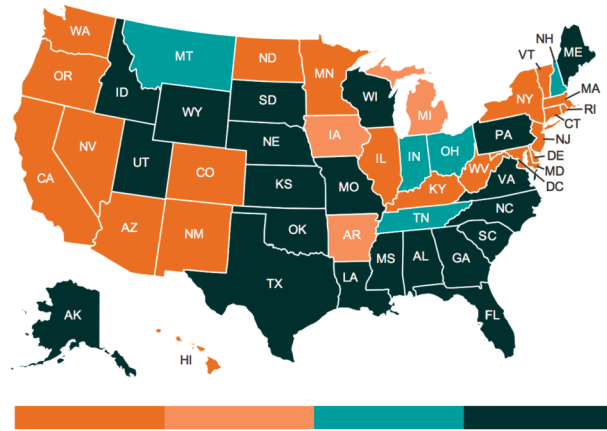
Last summer's Supreme Court decision on the Affordable Care Act made it optional for states to expand Medicaid eligibility to people with incomes up to 138 percent of the poverty level (about \$15,856 for an individual). To track Medicaid decisions at the state level, check out the map below showing which states are expanding, pursuing a customized expansion, or not expanding, and which states haven't yet decided. The map also offers state-level infographics, based on data from the Kaiser Commission on Medicaid and the Uninsured, highlighting the law's impact on the uninsured, with and without Medicaid expansion.

For interactive map go to:
<http://www.commonwealthfund.org/Maps-and-Data/Medicaid-Expansion-Map.aspx>

Or click on map.

Medicaid Expansion by State

Interact with the map below to see the impact of Medicaid expansion on a state's uninsured population

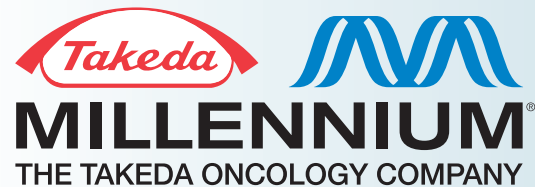
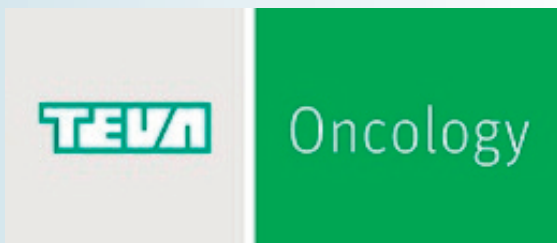


* Indiana and Tennessee have considered expanding with variation.

Data for state images based on J. Holahan, M. Buettgens, and S. Dorn's *The Cost of Not Expanding Medicaid*, Kaiser Commission on Medicaid and the Uninsured, July 2013. Others source for the map include Avalere State Reform Insights; Center of Budget and Policy Priorities; Politico.com; and Commonwealth Fund analysis.

Source: *The Commonwealth Fund: Connection*. August 5, 2013

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