



PCA3: A New Prostate Cancer Biomarker?

by Virgil Simons

In the words of Dr. Willet Whitmore: "Is cure possible for men in whom it is necessary? Is cure necessary for men in whom it is possible?" This is the conundrum faced by men, and many physicians, relative to the issue of testing for prostate cancer. While the current PSA test has unquestionably been a factor in the early detection of, and reduction in mortality from, prostate cancer, controversy over its use continues. Arguments against claim that it leads to too many unnecessary diagnostic procedures and treatment for tumors that would remain indolent and pose no threat to the patient's life. Advocates pro and con have clamored for a better biomarker that could differentiate between indolent and lethal disease.

That vehicle just may be here. The U.S. Food and Drug Administration (FDA) recently approved a new test, which has been successfully used in Europe, that can mitigate the need for repeat biopsies in diagnosing prostate cancer. Here to provide an in-depth understanding of this test is Dr. Hendrik van Poppel, Chairman of the Department of Urology, University Hospital Gasthuisberg, Katholieke Universiteit Leuven, Leuven, Belgium.

The Prostate Net: Dr. van Poppel, firstly, help us to understand the difference between the current PSA blood test and the PCA3, which is a urine test. What are we measuring with each and at what levels should concern be generated.

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Thoughts on the Preventive Services' Recommendation

by Virgil Simons

We are all — patients, advocates, professionals, legislators, and media — caught up in the controversy of the USPSTF's "D" recommendation for the PSA test. Firstly, let me clearly state that I am in complete favor of a man having access to, and being encouraged to have, a PSA test. If I had followed the USPSTF recommendation at the time of my Pca experience, then it's highly likely you would not be reading this column nor would The Prostate Net be in existence. I had no symptoms and had I followed my doctor's suggestion that I was too young to need the test (at 48), my surgical pathology Gleason 7 cancer would have continued to grow, metastasize and probably killed me.

The USPSTF says that PSA screening is not recommended for normally healthy men because of the potential risks for overtreatment and inconclusive data on survival benefit. Herein lies the true issue of the problem, which is not the test itself. The American Cancer Society in its response to the recommendation notes: "...we are concerned that many men will be harmed by undergoing screening that leads to detection and treatment of prostate cancers that would never have become clinically apparent (overdiagnosis and overtreatment)" (Editor's emphasis).

The American Urological Association and many advocates disagree with this position because benefit has been proven over the years of the PSA test's use seen in declining Pca-specific mortality and the ability to detect cancer earlier. They further state, "...the harms of PSA-based screening can, in fact, be minimized by good clinical practice."

The Prostate Cancer Foundation gave additional support by saying, "...the USPSTF's position provides a teachable and actionable moment for the medical community to improve targeting of PSA screening in patients, **reduce over-testing and improve processes of patient education** on the risks of overtreatment from PSA screening."

The core issue here is not the TEST, but the PROCESS that surrounds its awareness, implementation and subsequent therapeutic interventions. The PSA test should be imperative for every man as part of knowing his health status, not unlike being tested for diabetes, hypertension, cholesterol level, etc. Each of these tests are necessary for a man, his physician, and family to engage in a dialogue as to preventive and maintenance protocols needed to insure a healthy life that supports the individual and his family's objective for quality of life. But can this all be achieved in a system that allocates, on average, no more than 10 minutes per patient of the doctor's time to addressing the totality of his health concerns, much less engaging in a thorough discussion of PSA risks and benefits.

What resonates clearly throughout the overall commentary is that "good clinical practice" demands full disclosure between doctor and patients of risks associated with the disease AND the determination of it. But, in a system of healthcare wherein doctors are often measured by the number of patients seen, quantity of diagnostic tests ordered, how many treatment procedures are done and how much revenue is generated, we have to ask "What then is good clinical practice?" When we see urologic practices investing in radio therapeutic facilities, renting them out and then referring patients to them for "second opinions", can this be called interdisciplinary medicine? When the system rewards a physician disproportionately

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more for surgery versus active surveillance, when insurance pays more for therapeutic procedures versus preventive health management, we have to question the advocacy of pushing for a test protocol that can abuse the needs of those we serve. How can overdiagnosis and overtreatment be minimized when the presumptive threat of legal action by patients encourages physicians to run exhaustive diagnostics and "treat" any suspected cancer?

So, how do we make change happen? Pressure must be kept on our federal officials and legislators to fund more research into tools that will enable better identification of lethal versus indolent prostate cancer as well as more extensive support for disease risk awareness and education. However, growing up in the old Chicago political system, I know that local issues dictate political change. The example in the case of the **PSA test's use in New Jersey** (The Prostate Net's home) showed a state's action in ignoring federal recommendation in order to provide the necessary care for its citizens. Anne-Marie Slaughter, in a recent TIME magazine article commented on our healthcare system to say: "You've got a broken political system. You've got a culture that is very suspicious of Big Government provision. With the legacy of our private-enterprise health care — all these vested interests — you've got a perfect storm. Major change in health care is more likely to come from the bottom up, in terms of individual states, than from the top down."

We must therefore start with ourselves in taking responsibility for our health by understanding the risks we face from genetics, environment and lifestyle; we must insure that we have access to healthcare for ourselves and our families; we must become informed consumers regarding that health care to know that any test and/or procedure is necessary and with value; we must engage our doctors to inform them of our desires for quality of life and choices as to how it should be attained and maintained; and we must be even more part of the political process to get the government we need. Dr. Willet Whitmore provided a basis for our imperative: "For a patient with prostate cancer, if treatment for cure is necessary, is it possible? If possible, is it necessary?" This, I believe, is the charge when looking at the full spectrum of prostate cancer in America.

The following are some resources to help make informed choice on the PSA test

http://www.auanet.org/content/health-policy/government-relations-andadvocacy/in-the-news/uspstf-psa-recommendations.cfm?WT.mc_id=EML6621MKT

http://palpable-prostate.blogspot.com.es/2011/10/uspstf-draftreport.html?spref=fb_

http://www.youtube.com/watch?v=oE4AtFqCX5k

http://www.cancer.org/Cancer/news/News/task-force-recommends-againstroutine-prostate-cancer-screenin_

http://www.medscape.com/viewarticle/766662?src=mp&spon=15

http://www.prnewswire.com/news-releases/aua-disputes-panelsrecommendations-on-prostate-cancer-screening-152349275.html

http://www.pcf.org/site/c.leJRIROrEpH/b.8095479/k.CCC/USPSTF_Panel_An_ nounces_Final_Recommendation_Against_PSA_Screening_for_Prostate_Cancer. htm_

http://www.pcf.org/site/c.leJRIROrEpH/b.7865923/k.DAB1/PCF_submits_co mments_to_USPSTF_regarding_PSAbased_screening.htm

http://www.ivanhoe.com/channels/p_channelstory.cfm?storyid=29364



Quote From Rep. Marsha Blackburn Re: USPSTF Transparency Act

"[This act] would require common sense coordination among relevant agencies and stakeholders while restoring the doctorpatient relationship. The American people are tired of a government that believes it knows what is best for you, your health, and your wallet. The critical nature of the Task Force's work, and the widespread impact to public health, is better served by a Task Force that is patient-centered."



Rep. Marsha Blackburn

TAK-700 Trial Seeking Participants

TAK-700 is an oral medication that targets and inhibits a key enzyme in hormone production. It was shown in an earlier clinical trial to decrease PSA and testosterone levels.

Another trial is underway that will compare the effectiveness of TAK-700 and prednisone vs. prednisone alone in men who have previously received chemotherapy.

If future trials confirm it, TAK-700 might be used early on to delay chemotherapy and extend the lives of men with metastatic prostate cancer. For more information, go to <u>www.elmpctrials.com</u>

Cancer Support Community

A few years ago, two innovative and active cancer support organizations, Gilda's Club and The Wellness Community, joined together to form the Cancer Support Community. This grassroots network has over 50 local affiliates and 100 locations around the world. Their mission is to provide social and emotional help to those living with a cancer diagnosis by providing information and resources, acting together to effect change, and supporting the cancer community. For more information, go to cancersupportcommunity.org or get CancerSupportSource, a free app for the iPhone. You can also call 1-888-793-9355.

New Legislation To Make USPSTF More Transparent

Washington, DC, June 22, 2012 – The Prostate Cancer Roundtable commends Congressmen Marsha Blackburn and John Barrow for their introduction of H.R. 5998 the USPSTF Transparency and Accountability Act of 2012.

The bill is designed to reform a process whose flaws were highlighted by the recent prostate cancer screening recommendation process. The Task Force failed to consider input from patient representatives and medical specialists. The Task force also failed to reach out to other federal agencies conducting research on prostate cancer screening, and heavily relied on a study that has been universally criticized as being critically flawed.

"Patient representatives and medical specialists and stakeholders in the topic area under study need to be a part of the process of developing recommendations. This legislation will establish and advisory board to do just that," stated Merel Nissenberg, President of the National Alliance of State Prostate Cancer Coalitions.

"The recent prostate cancer screening recommendation by the Task Force largely ignored the benefits of screening for men known to be a high risk, including African American men, men with a family history of prostate cancer, veterans exposed to Agent Orange, and men with an above-average baseline PSA in their 40s. this legislation will require the Task Fore to provide greater consideration of high-risk populations" stated Thomas Farrington, President of the Prostate Health Education Network.

The above statement has been issued on behalf of and endorsed by the following Prostate Cancer Roundtable member organizations.

- Ed Randall's Fans for the Cure
- Malecare Prostate Cancer Support
- Men's Health Network
- National Alliance of State Prostate Cancer Coalitions
- Prostate Conditions Education Council
- Prostate Health Education Network
- The Prostate Net
- Us TOO International Prostate Cancer Education and Support Network
- Women Against Prostate Cancer
- ZERO The Project to End Prostate Cancer

Help for the Uninsured

The Patient Advocate Foundation has recently produced a brochure, "National Uninsured Resource Directory: Find The Missing Pieces" that will be an educational tool to inform uninsured consumers of their options as well as to provide tips on navigating the healthcare system.

Copies of the brochure can be obtained by contacting the Patient Advocate Foundation at: 1.800.532.5274 or accessing it online at: www.patientadvocate.org/resources



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HVP: The major difference between PCA3 and PSA is the fact that PCA3 is prostate cancer-specific and PSA is not.

PSA is a protein produced by the prostate. It may be found in an increased amount in the blood of men who have prostate cancer but also in men who have benign conditions of the prostate such as benign prostatic hyperplasia (BPH) or inflammation of the prostate (prostatitis). This is due to the fact that PSA



Dr. Hendrik van Poppel

is not only produced by cancerous prostate cells but also by non-cancerous prostate cells. The greater the number of prostate cells / size of the prostate, the higher the PSA level in the blood. A high PSA level may thus not necessarily mean that there is prostate cancer present. The high PSA level could also be due to BPH or prostatitis.

PCA3 (Prostate Cancer gene 3) is a gene that is highly overexpressed in prostate cancer tissue compared to benign prostate tissue. It is unlike PSA, only expressed in prostate cancer cells and thus prostate-cancer specific. PCA3 is also not affected by prostate size. The PCA3 test measures PCA3 in a urine sample. The PCA3 Score indicates the probability that prostate cancer will be found in the biopsy.

In response to your question about at what PSA and PCA3 Score levels we should be concerned, I would first like to comment that prostate cancer diagnosis is based on a combination of risk factors. We do not only look at the patient's PSA level, but also consider amongst others the patient's age, the outcome of the digital rectal examination (DRE) and whether there is prostate cancer in the family. In addition, the prostate size is important. The PCA3 test is a new additional test to help in the diagnosis of prostate cancer. Based on all risk factors we decide whether a prostate biopsy for diagnosis of prostate cancer is necessary or can be delayed.

As the PSA level is age-dependent and should be considered together with other prostate cancer risk factors, it is difficult to define a level at which we should be concerned. Also the PCA3 Score should be looked at in combination with other prostate cancer risk factors. A lower PCA3 Score corresponds with a lower probability of finding prostate cancer in the repeat biopsy. Generally a PCA3 score <25 is associated with a decreased likelihood of a positive repeat biopsy. However, it should be noted that a 'negative' PCA3 Score, i.e. a PCA3 Score <25 doesn't guarantee for 100% that prostate cancer is not present in the biopsy. Even with a PCA3 Score <25 or <10, there is still the small possibility that prostate cancer is present, and this could also be aggressive cancer.

TPN: The PSA test is not really a measure of prostate cancer, but an indicator, if an abnormal level is noted, of "something" happening within the prostate that could range from an infection to an enlarged prostate to prostate cancer. The PCA3 is supposedly prostate cancer specific; does it act like the test being used for advanced stage prostate cancer that measures Circulating Tumor Cells (CTC)?

HVP: Circulating tumor cells (CTCs) are cells that have detached from a primary tumor and circulate in the bloodstream. CTCs may constitute seeds for subsequent growth of additional tumors (metastasis) in different tissues. CTCs can be measured with specific tests in men who have advanced or metastatic prostate cancer and may be prognostic for overall survival.

PCA3 is a gene that is expressed in prostate cancer cells but does not code for a protein. It does not circulate in the body and does not cause metastasis. It is used in men in conjunction with other patient information to aid in the decision for repeat biopsy in men 50 years of age or older who have had one or more previous negative prostate biopsies. The PCA3 test measures the PCA3 mRNA concentration in urine samples. The test starts with a DRE of the prostate. This allows prostate cells (with potential PCA3 mRNA) to be shed into the urine. The urine sample is analysed by the laboratory that measures the PCA3 mRNA concentration and calculates the PCA3 Score.

TPN: In the U.S. approval was given to evaluate the need for a repeat biopsy in men who had a previous negative biopsy. Has that been the European experience?

HVP: In both Europe and the U.S. several clinical studies with the PCA3 test have been performed, both in men undergoing a first biopsy and in men undergoing a repeat biopsy. In addition, there has been a lot of clinical experience with the PCA3 test in Europe. Indeed, the PCA3 test has shown most useful for helping decide whether a repeat biopsy is needed after one or more negative biopsies.

TPN: Is there a numerical range, similar to PSA levels, that indicate an abnormal condition warranting a biopsy and how aligned with the probability of a prostate cancer diagnosis is that level.

HVP: The PCA3 Score has a continuous range. A high PCA3 Score indicates a high probability of prostate cancer in the prostate biopsy. A low PCA3 Score indicates a low probability of prostate cancer in the biopsy. It has been shown that a PCA3 Score <25 is associated with a decreased likelihood of a positive biopsy. In a clinical study of 466 men (50 years or older) who had 1 or more prior negative biopsies and who were recommended a repeat biopsy, 49.6% of men had PCA3 Scores <25 [Ward J, et al. Presented at AUA Annual Meeting, 19-23 May 2012, Atlanta, GA, US]. Of these 231 men, 208 (90%) subsequently had a negative biopsy result, while 23 (10%) had a biopsy positive for prostate cancer. For the 235 men with PCA3 Scores \geq 25, the PCA3 test result supported the decision to repeat biopsy; 34% (79/235) of these men had positive biopsies. Men with PCA3 Scores <25 were 4.6 times more likely to have a negative repeat biopsy than men with PCA3 scores \geq 25. The clinical benefit of the PCA3 test is thus that at a PCA3 Score cut-off of 25, 50% of repeat prostate biopsies could have been avoided. However, as noted before,



Walking Away from the Abyss

By Virgil Simons

Bishop T. D. (Thomas Dexter) Jakes is an internationally known religious leader, founder and chief pastor of *The Potter's House*, who touches over 30,000 people weekly through his mega church in Dallas. He is an inspirational visionary who uses emerging technologies to reach almost another 1 million "congregants" on Twitter and Facebook. Most critically, he understands that often economic choices can have influence on personal religiosity; he has built a business empire to enable him to spread God's messages of hope and healing.



It is in this latter role that we speak with Bishop Jakes to learn about a new program that can provide economic benefit for those

Bishop Jakes

needing medications for illness, maintenance and/or preventive care. Here is that interview:

Virgil Simons: Bishop, most of us know you as a famous personality, who has the ears of politicians and business leaders, and has enterprises reaching much of the world. But, what set you on this path; what person, moment gave you the vision and/or inspiration to become who you are today?

Bishop T. D. Jakes: (With a bit of a laugh in his voice..) Growing up in West Virginia there were challenges to me and my family, but I believed in trying to attain a goal of making contributions to the generations in every way that I could, but, more importantly, helping others to help themselves.

VS: In your sermons and teachings you emphasize the importance of the individual being able to look into himself or herself to find the strength, knowledge to complete themselves and to move forward. Since we're speaking about health today, how would you guide someone towards health-seeking behavior?

TDJ: Having good health has been paramount in my life. My father died of renal failure, I have an on-going renal problem, and I have hypertension, which I must continually monitor. In matters of personal health, we must be open and exemplary in our dialogues with our doctors, family, friends and community. We must not let fears and presumptions about health keep us in the shadows from seeking the best possible lives for ourselves. We need to utilize all of the relevant diagnostic tests (PSA, HIV, cholesterol, BMI, blood pressure, etc.) to help insure we can live the lives God has intended for us.

VS: Oftentimes when we work in the community and talk about the importance of early detection of prostate cancer or breast cancer, people will say to us, "If God wants me to have cancer, then I'll have it; and, if I die from it, that's His will." What would you say to these people?

TDJ: We need to stay in touch with our faith. God blesses us with a body that is His temple, and we have a responsibility to it. Many of the media influences to

which people are exposed promote and hype the polarity and differences resulting from socioeconomic inequities. Without faith, people can fall into an abyss of human depravity and despondency; we must continue to remind them,

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and ourselves, not to lose hope, for that is our ultimate motivation. And that's where our leaders in churches, in companies, and in government can play an important role. Leaders must admit their own vulnerabilities and mortality in order to speak openly to their constituencies to help guide them toward the health they deserve.

Politicians particularly have a responsibility to those who've hired them. There is too much response being given to special interests. The system needs to be overhauled and our representatives need to bite the bullet in realizing that there isn't a "magic bullet" to be found in any one person or party from which change will spring. We have too much of an economy focused on consumption and not enough long-term vision on making corrections for the good and influencing providers to make choices for the good of the country. They can't remain lethargic in working to salvage the promise of America for all of our citizens.

VS: We specifically wanted to speak about your recently launched PharmaCard project. Please tell us about it.

TDJ: Health awareness, and the necessity of every family to seek it, has long been part of our ministry. There are medical departments in each of our churches, we have a gym onsite for our employees and staff, we confer regularly with medical specialists to gain perspective on issues such as, the appropriateness of PSA and other testing, we have worked to dispel the myths surrounding disease, such as HIV/AIDS, and we have taken our message out to the people. Our "Manpower" conference

(<u>http://www.manpowerconference.org/</u>) is designed to help all men discover their God-given gifts and talents; "Woman Thou Art Loosed"

(<u>http://www.wtal.org/</u>) provides a forum for women who have overcome any obstacle or are looking to transform their lives. As much as we speak to those we lead, so do we also address those charged with leadership in our "International Pastors & Leadership" conference

(http://www.pastorsandleaders.org/). We must put our faith into action.

With our Pharmacy Discount Card (<u>http://connectionsrx.com/</u>) we seek to address those economic conditions that have forced people to make hard choices in their lives: medication versus diapers; prescriptions versus rent or food; health today versus future lives. The program provides every participant, regardless of income or insurance status, with a mechanism to achieve major cost savings on the cost of their medications, thereby encouraging them to take those meds and have a healthier and better life. We have used our business contacts to do what we can to contribute to this and future generations and to truly help others to help themselves.

Editor's Note: For more information on Bishop Jakes and his initiatives, go to: <u>http://www.tdjakes.org/</u> or call: **1-800-BISHOP2**



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the decision to perform a biopsy does not only depend on the PCA3 Score but should be made in combination with other prostate cancer risk factors such as age, PSA level, prostate size, outcome of DRE, family history of prostate cancer.

TPN: Again, as with the PSA, the question has to be asked, "Can this test distinguish between indolent and lethal prostate cancer?"

HVP: Recent studies suggest that the PCA3 Score may differentiate between significant/aggressive and non-significant/indolent cancer. The PCA3 Score has shown to predict small tumor volume and insignificant prostate cancer independent of other risk factors [Auprich M, et al. Eur Urol 2011;60:1045-54]. Therefore if cancer is found in the biopsy, the PCA3 Score may give additional information about the significance/aggressiveness of the cancer. This can aid in the decision on treatment, e.g. if active treatment like surgery or radiotherapy is needed or if active surveillance (monitoring potential cancer progression by means of DRE, PSA and/or PCA3) is an alternative. The lower the PCA3 Score, the greater the probability that the cancer is indolent.

When comparing clinical studies, it appears that the median PCA3 score was around 20 in men with 'indolent' prostate cancer and around 50 in men with 'significant' prostate cancer [van Poppel H, et al. BJU Int 2011;109:360-6]. It can thus be suggested that if cancer is found in the biopsy, a PCA3 score < 20is likely to indicate that this is indolent prostate cancer and that active surveillance may be a valid (first) treatment option. It should be noted that in the decision which therapy is most appropriate, other factors that give an indication on cancer significance should certainly be taken into consideration, e.g. the Gleason sum found in the biopsy specimen, the tumour volume and the clinical stage.

TPN: Data from the clinical study showed a 90% correlation between a negative predictive value and an accuracy that a negative biopsy would result in 90% of the incidences noted. Given this, is the PROGENSA PCA3 assay a potential replacement for PSA in early detection of prostate cancer?

HVP: The PCA3 test is not intended to be or become a replacement for PSA. It is a new test to be used in conjunction with PSA and other risk factors to guide biopsy decisions in men at risk of prostate cancer who have had prior negative biopsies.

TPN: In your practice and experience, what type(s) of patient would most benefit from use of this test.

HVP: Obviously the PCA3 test is of areat use to patients who have had one or more prior negative biopsies but in whom there is continued suspicion of prostate cancer, for example because of an elevated PSA level. It may help in deciding whether a repeat biopsy is necessary or may be delayed.

However, there are in my opinion also several other groups of patients who may benefit of the PCA3 test. These include:

- patients who have had a prior biopsy that showed presence of high grade prostatic intraepithelial neoplasia (HGPIN)
- patients with prostatitis and elevated PSA levels
- patients who are very anxious about harbouring prostate cancer, but are at low risk (e.g. low PSA level). The PCA3 test gives these patients additional information about the probability that prostate cancer is present, if a biopsy would be performed
- patients with a family history of prostate cancer, before the first biopsy

In addition, patients in whom prostate cancer has been found in the biopsy may also benefit from the PCA3 test. The PCA3 Score may provide additional information about the aggressiveness of the cancer and aid in the decision whether active surveillance is an appropriate first treatment option or if active therapy is necessary.

Thank you, Dr. van Poppel!!

Editor's Note: For additional information on the PCA3 test, visit: www.PCA3.org or: http://www.gen-probe.com/products-services/progensapca3

To view information on Dr. van Poppel's research on PCA3, go to: http://www.researchgate.net/researcher/63049844 Hendrik Van Poppel

The Harm We Do...

By Virgil Simons

There are many who will criticize me for this article on, and endorsement of, Dr. Otis Brawley's book, "How We Do Harm: A Doctor Breaks Ranks About Being Sick in America". Perhaps because we both grew up in the inner cities of the North and are products of Jesuit education, but I believe it's because we need to look at empirical evidence of a problem versus an emotional response to a situation.

Make no mistake, I am an advocate for the well-being of prostate cancer patients

the well-being of prostate cancer patients **Dr. Otis Brawley** and value the necessity of the PSA test; however, while having saved countless lives, including mine, it has been a vehicle for overuse/abuse by many in the medical establishment. When we have a system that rewards doctors for the number of patients seen, quantity of diagnostics done, and for how many treatment procedures are done, then we have to question ourselves as to what we are promoting and is there a better way to achieve our goals.





The Harm We Do...

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Dr. Brawley's book exposes many of those situations wherein patient benefit is compromised by financial encumbrances from lack of insurance to minimal access to care to overtreatment. The opening paragraph of the book hooked me into reading it in one sitting:

"She walks through the emergency-room doors sometime in the early morning. In a plastic bag, she carries an object wrapped in a moist towel. She is not bleeding. She is not in shock. Her vital signs are okay. There is no reason to think that she will collapse on the spot. Since she is not truly an emergency patient, she is triaged to the back of the line, and other folks, those in immediate distress, get in for treatment ahead of her. She waits on a gurney in a cavernous green hallway. The "chief complaint" on her chart at Grady Memorial Hospital, in Downtown Atlanta, might have set off a wave of nausea in a hospital at a white suburb or almost any place in the civilized world. It reads, "My breast has fallen off. Can you reattach it?"

In an interview in Atlanta magazine, Dr. Brawley provides some important insights on America's healthcare system:

"I actually think we need to transform how we think of healthcare. Most of it is

about responding to illness, not about preventing illness in the first place. Last year healthcare costs were 17.5 percent of our gross domestic product. That's one and a half times the amount in the next most expensive country. If healthcare costs keep growing at the present rate, they'll be 25 percent of our GDP by 2025. Healthcare is choking our economy."

"When we look at outcomes, such as life expectancy, we rank fiftieth. We do not get what we pay for out of our healthcare system."

"We need to change how we reimburse for care. We need to reimburse doctors

S WERE RELIVITY ALD to coach patients about leading a healthy life. We pay doctors tremendously for

sticking things into people and cutting on them, and instead we need to reimburse for teaching patients. I don't see health promotion happening in the United States."

We need to continue to advocate for better diagnostics in order to determine lethal prostate cancer from that which won't kill you. We need to work to preserve use of the PSA test until a better marker is found. But we need to inform ourselves and our constituencies that the system is not totally in their favor and that they must be their own best advocates to insure the health and quality of life they desire and deserve. This book can be an important step in gaining that understanding.

Tools To Conquer Cancer: ASCO 2012

June, 2012

It was my privilege to attend the American Society of Clinical Oncologists' conference again this year. After five days of attending research presentations and searching through some 4500 abstracts, I've found some general themes and exciting research that I want to share with you:

Key Abstracts and Presentations.

Intermittent (IAD) versus continuous androgen deprivation (CAD) in hormone sensitive metastatic prostate cancer (HSM1PC) patients



Diane Johnson

Bv Diane Johnson

(pts): Results of S9346 (INT-0162), an international phase III trial.

In hormone sensitive metastatic prostate cancer patients, IAD is not proven to be noninferior to CAD. For extensive disease patients IAD was noninferior; however, IAD was statistically inferior in minimal disease patients suggesting that CAD is the preferred treatment in this group. (see:

http://meeting.ascopubs.org/cgi/content/abstract/30/18_suppl/4?sid=4e 7520db-0db4-4042-8010-d67019a8f445 for full abstract. This was one of the most important, and controversial, presentations of the conference for its implications for practice-changing recommendations.

Abiraterone acetate (Zytiga) — Two studies that evaluated the efficacy of abiraterone acetate (Zytiga) were presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in June this year. Although other studies are still on-going, these indicate significant promise in the treatment of men with prostate cancer. Zytiga, approved in both the U.S. and Europe last year to treat men with advanced prostate cancer, acts by inhibiting the production of testosterone in the testes, adrenal glands and prostate tumor tissue.

The first study, led by Mary-Ellen Taplin, MD of Dana-Farber Cancer Institute, looked at a small group of men with potentially aggressive prostate cancer that hadn't spread outside of the prostate. 56 men were given a common hormone therapy, leuprolide, plus either Zytiga or a placebo for 6 months before prostate surgery. When the prostate tissues were examined after surgery, 34% (10 men) had nearly complete elimination of the cancer. Larger studies are needed to verify these results. The abstract of this study can be seen at:

http://meeting.ascopubs.org/cgi/content/abstract/30/15 suppl/4521?sid =f2668a8d-f10f-43b5-a8db-37801eccd690

Charles J. Ryan, MD of University of California, San Francisco, presented a study of 1,088 men with metastatic castrate-resistant prostate cancer (advanced

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Gentlemen Check Your Engines[™]…in Latham, NY

By Diane Johnson

Sometimes it's hard to get a guy's attention. It seems most men would rather talk about their bike, car or truck than their health. At least that's the theory behind The Prostate Center of Community Care Physicians drawing last

September 13th for a free 2010 Victory Hammer 8-ball motorcycle. "Our goal with this campaign is to create a buzz around the free bike drawing so we can raise awareness of prostate cancer and make it a part of men's conversations," says Robert Desiardins.



Operations Manager of The Prostate Center in Latham, NY.

In partnership with the American Cancer Society (<u>www.cancer.org</u>) and The Prostate Net (<u>www.theprostatenet.org</u>), this awareness campaign says it's time for men to 'check their [own] engines' too. "We know men like bikes and cars...and a large portion of...motorcycle riders are 45 years or older—the same age when men should be talking to their doctors about prostate screening," added Mr. Desjardins. The Prostate Center of Community Care Physicians offers free prostate cancer screenings, including PSA blood testing and a digital rectal exam, every Friday from 8am to 4pm at the Capital Region Health Park in Latham. Walk-ins are also welcome during regular business hours on Fridays, 8 a.m. to 4 p.m., at The Prostate Center in Latham, NY.

The event drew several thousand entrants and more than 300 hundred men in for information and/or screening. For more information on this event, contact Alexis Musto, Marketing Manager at Community Care Physicians, by phone at 518.213.0322 or by email at <u>amusto@communitycare.com</u>. To schedule an appointment for a free prostate screening at The Prostate Center of Community Care Physicians, PC, call 518.640.6789 or go to TheProstateCenter.org

Checking Your Engines....in Detroit

By Virgil Simons

On June 9th of this year key stakeholders came together in Wolverine country to launch the Gentlemen Check Your Engines program in the Detroit Metro area.

The event was sponsored by the Karmanos Cancer Center and Wayne State University Medical Center in partnership with The Prostate Net and Us Too International. The event was held at Wolverine Harley-Davidson and drew more than 200 men and women for a day of information and fun.

Lead by Dr. Elisabeth Heath, the Karmanos team brought important information on prevention of breast and prostate cancer, early detection of cancer,



blood pressure screening, tobacco *Gerald Blaskey and Dr. Elisabeth Heath* cessation and risk assessment testing for heart attack and stroke. Coupled with the free custom bandanas, chocolate motorcycles and plentiful food, it added up to a day of enjoyment and health enlightenment.



Karmanos

New Video on Advanced Pca Treatment

Dr. Tomasz Beer has recently produced a comprehensive video discussion on all the principal current treatments and the most promising emerging drugs for advanced prostate cancer. In this talk, he discusses hormonal agents including abiraterone and MDV-3100, chemotherapy drugs including docetaxel and cabazitaxel, immunologic therapy with sipuleucel-T, biologic therapy with XL-184, and bone targeted therapy with alpharadin. You can access the video from:

http://www.cancer-clinical-trials.com/2012/05/video-latest-developments-inadvanced.html



Tools To Conquer Cancer: ASCO 2012

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cancer previously treated with hormone therapy, but no longer responding) with mild or no symptoms who had not received chemotherapy. They were given Zytiga, or a placebo, plus prednisone. In the Zytiga arm, both progression-free survival and overall survival were significantly improved, indicating that the use of this androgen inhibitor could delay chemotherapy. The results were so promising that the study was stopped early and those in the placebo arm were offered Zytiga. Details of this

study can be seen at:

http://meeting.ascopubs.org/cgi/content/abstract/30/18_suppl/LBA4518?sid =4e7520db-0db4-4042-8010-d67019a8f445_

MDV3100 – Several studies were discussed that showed the benefit of this drug in various stages of prostate cancer alone and in combination with other therapeutic agents.

Effect of MDV3100, an androgen receptor signaling inhibitor (ARSI), on overall survival in patients with prostate cancer postdocetaxel: Results from the phase III AFFIRM study. MDV3100, a novel ARSI, significantly improves OS in men with postdocetaxel-treated CRPC reducing the risk of death by 37% relative to placebo. The IDMC determined the risk:benefit of MDV3100 was favorable and recommended the phase III AFFIRM

trial be unblinded. Details of the study can be seen at:

http://meeting.ascopubs.org/cgi/content/abstract/30/5_suppl/LBA1

Antitumor activity of MDV3100 in pre- and post-docetaxel advanced prostate cancer: Long-term follow-up of a phase I/II study. MDV3100 demonstrates durable anti-tumor activity in patients with CRPC both before and after chemotherapy. Based on these promising results MDV3100 is currently being evaluated in two global phase III studies in patients with metastatic CRPC, the AFFIRM study in patients previously treated with docetaxel and the PREVAIL study in chemotherapy-naïve patients who have progressed on androgen deprivation therapy. Details at:

http://meeting.ascopubs.org/cgi/content/abstract/29/7_suppl/134

A phase II, open-label, single-arm, efficacy, and safety study of MDV3100 in patients with hormone-naïve prostate cancer. This is a phase II study of MDV3100 in men with hormone-naïve PCa (HNPCa) who are candidates for ADT. It is an evaluation of the drug's potential for men with earlier stage prostate cancer. Details at:

http://meeting.ascopubs.org/cgi/content/abstract/29/7_suppl/177

TAK-700 (orteronel) — is a selective inhibitor of 17,20-lyase, a key enzyme in the testosterone synthesis pathway. In a phase 1/2 study in men with mCRPC, orteronel reduced prostate-specific antigen (PSA) levels, and inhibited testosterone and DHEA-S consistent with potent 17,20-lyase inhibition.

A phase III, randomized study of the investigational agent TAK-700 plus prednisone for patients with chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC). This

randomized, double-blind, placebo-controlled multicenter study is investigating efficacy and safety of TAK-700 plus prednisone vs placebo plus prednisone in patients with mCRPC who have not received prior chemotherapy. This will enable evaluation of TAK-700 at an early stage of mCRPC, where it may be more effective and delay the need for chemotherapy. Details at:

http://meeting.ascopubs.org/cgi/content/abstract/29/15_suppl/TPS184_

A phase III, randomized, double-blind, multicenter trial comparing the investigational agent orteronel (TAK-700) plus prednisone (P) with placebo plus P in patients with metastatic castrationresistant prostate cancer (mCRPC) that has progressed during or following docetaxel-based therapy. This double-blind, multicenter study is assessing orteronel + P vs placebo + P in men with mCRPC. Patients must have evidence of disease progression during or after receiving docetaxel. Details can be found at:

http://meeting.ascopubs.org/cgi/content/abstract/30/15_suppl/TPS4693

Radium 223 chloride (Ra-223)— a targeted alpha-emitter, targets bone metastases (mets) with high-energy alpha-particles of short range.

Updated analysis of the phase III, double-blind, randomized, multinational study of radium-223 chloride in castration-resistant prostate cancer (CRPC) patients with bone metastases

(ALSYMPCA). ALSYMPCA, a phase III double-blind, randomized, multinational study, compared Ra-223 plus best standard of care (BSC) vs placebo plus BSC in CRPC patients (pts) with bone mets. The median overall survival (OS) benefit for Ra-223 increased from 2.8 to 3.6 months, with a hazard ratio of 0.695 (i.e., 30.5% reduction in risk of death). Ra-223 is an effective therapy that improves OS and time to first SRE (skeletal related event) with a highly favorable safety profile, and may provide a new standard of care for CRPC patients with bone mets. Details at: http://meeting.ascopubs.org/cgi/content/abstract/30/18_suppl/LBA4512

Other key points from the conference:

The focus of research must change.

In the past, research used to focus on organ type, then on tumor type. Future research needs to shift to the molecular pathways driving the cancers.

Tumors must be understood on a biological level.

There can be different regions within the same tumor, with different characteristics and prognoses.

Better predictive tools are needed.

The goal is to define each person's risk level, so treatment can be individualized.

Circulating Tumor Cells (CTC's)—Specific biomarkers are needed to determine the extent of prostate disease. Tumor cells can circulate in the bloodstream and may establish metastases outside of the prostate, usually in the bone. There are numerous studies underway to monitor and measure these cells in an attempt to learn more about the biology of the disease. As a prostate cancer biomarker, CTC's could help doctors and their patients make more appropriate treatment decisions.

In the opening session, Dr. Michael P. Link, MD, outgoing ASCO President, shared some of the lessons he has learned from his work in pediatric cancer: high quality care requires collaboration and research cures cancer. Most importantly, he said, "We must learn from every patient." The 30,000 members of ASCO are still focused and working hard every day to conquer cancer. And they will, with your help.



Postdoctoral Positions at Center for Cancer Research and Therapeutic Development, Clark Atlanta University

Two (2) post-doctoral positions are available immediately to study cellular and molecular biology of prostate cancer at the Center for Cancer Research and Therapeutic Development (CCRTD) at Clark Atlanta University. The selected candidates will be expected to perform cutting edge research in prostate cancer. The selected candidates will carry out research work in one of the following areas: AR and growth factor signaling, cell proliferation, invasion, metastasis and/or angiogenesis. Applicants should possess a solid knowledge in cancer cell and molecular biology. A Ph.D. degree in biological sciences and 2 to 3 years of research experience in relevant areas is required. For inquiries, contact Dr. Shafiq A. Khan, Director, Center for Cancer Research and Therapeutic Development at 404-880-6795 or via e-mail at skhan@cau.edu <mailto:skhan@cau.edu>.

When applying for position, please reference Position No. 121-12 and submit resume and the names, addresses and telephone numbers of three references to: Clark Atlanta University Office of Human Resources, 223 James P. Brawley Drive, SW, Atlanta, Georgia 30314.

MyLifeline.org

MyLifeline.org was founded in 2007 as an online community for cancer patients. Today, people all over the world—patients, families, caregivers and friends—connect to offer free, personal private websites that provide a strong, caring community. They offer various tools to help navigate this complex and stressful journey: the Helping Calendar lets you schedule chemotherapy and radiation treatments and ask a friend to go along; the Learning Links let patients share information on their specific cancer type; patients can set up a personal fundraiser on the Giving Angels page; Member Updates and Guest Messages can also be shared. Prescription assistance and survivorship tools are also being developed.

MyLifeline.org focuses 100% on cancer and believes that "a strong community is critical for healing." It is an important tool for caregivers also, because it provides all the tools needed for the treatment process and communications. Their motto is "No patient should feel alone." Contact <u>MyLifeline.org</u> for more information or get the <u>MyLifeline.org</u> app for the iPhone.

A Ride for Life: A Survivor's Story

Rudy Lombard, PhD is on the faculty of the Department of Medical Social Science at Northwestern University, a Member of the External Advisory Board of the Prostate Cancer Biorepository Network and a survivor of prostate cancer. His journey from diagnosis to survivorship has been chronicled in presentations to cancer research and patient groups throughout the country. But we want to talk about a different "Ride" that brought Rudy to the forefront of American Life.



Rudy Lombard established himself as an anti-racist activist in Catholic elementary school, leading children to play in a deserted "whites-only" playground. He had to battle the nuns in high school to obtain his scholarship to the University of Michigan. After finding that his parents had taken extra janitorial jobs to support his scholarship to Ann Arbor, Rudy transferred back to Louisiana, intending to become a labor leader in the waterfront unions. He was about to join the NAACP, when he found they were against sit-ins. He became an early leader in the New Orleans chapter of the Congress of Racial Equality (CORE). On September 17, 1960, CORE chairman Rudy Lombard, Tulane student Sydney "Lanny" Goldfinch, Oretha Castle, and Dillard student Cecil Carter sat at the lunch counter at McCrory's department store on Canal Street. They were arrested.

"Yes. Back then I was deeply involved: Sit-ins, Freedom Rides, Mississippi Summer in Philadelphia (MS) where the students Chaney, Goodman, and Schwerner were killed, and all the rest... There is a landmark Public Accommodation case that was adjudicated in the U.S. Supreme Court (1965) which is titled, Lombard vs, Louisiana, which grew out of the student sit-in demonstrations in New Orleans", recalls Rudy; "but the struggle today against health disparities, equal access to care, and true health reform is not too different from the fight for equality in Civil Rights 50 years ago."

Too often as citizens we take for granted our way of life; there is a mounting struggle over healthcare that we all must be a part of; become aware, become knowledgable, become involved in the process to insure that we and our children have the best care possible made available equitably to all.

A video interview with Dr. Lombard can be seen at: http://mediasuite.multicastmedia.com/player.php?v=l4170140

CancerCare's Financial Assistance Program

If you are in need of financial assistance, you can contact *CancerCare*. Call their toll-free Hopeline at 800-813-HOPE (4673) to speak to one of their oncology social workers. They will help you complete an application. Their hours are Monday to Thursday, 9am to 7pm ET and Friday, 9am to 5pm ET. You can view an application and get more information on their website, <u>cancercare.org</u>.

Symposium Registration Information

Please complete this form, save it and email it as an attachment to <u>support@prostatenet.org</u> or complete it, print and mail to: Prostate Net, P. O. Box 10188-#77550, Newark, NJ 07101-3188

Name (Please list name as you wish it to appear)

Address				
City, State and Zip				
Contact Telephone # (Required)				
Contact Email (Required)				
Category (Please circle all that are appli PATIENT / SURVIVOR UROLOGIST				
Registration for the Symposium is Free! Please indicate the location for which you are registering (NOTE – a separate registration form is required for each person attending): September 8 – PROSTATE CANCER SYMPOSIUM – Chicago, IL; Northwestern University Lurie Cancer Center				
September 22 –	PROSTATE CANCER SYMPOSIUM – Detroit, MI; Karmanos Cancer Center 🔲			
October 20 –	PROSTATE CANCER SYMPOSIUM – New York, NY; The Prostate Net Location TBD 🔲			
November 3 –	PROSTATE CANCER SYMPOSIUM – Nassau, Bahamas; The Superclub Breezes Resort 🔲			
November 10 –	PROSTATE CANCER SYMPOSIUM – Jacksonville, FL; Mayo Clinic 🔲			
November TBD –	PROSTATE CANCER SYMPOSIUM – Philadelphia, PA; Kimmel Cancer Center at Jefferson 🔲			

Please return completed forms to: The Prostate Net Email: <u>support@prostatenet.org</u> For more information: 1-888-477-6763

Fax: 270-294-1565

