

*In The*

# Know

Confronting Prostate Cancer

August 2015

## Racial Health Disparity and the Shortage of African-American Doctors

A recent article in the Journal of Clinical Oncology reported that in 2013 only 2.3% of oncologists in the U.S. were African-American, and “ that African Americans will likely continue to be seriously under-represented in medical oncology”.

This is an issue of major relevance given the disproportionate incidence and mortality rate of cancer within the African-American population. While the rates for surgeons and family medicine doctors has been increasing, the shortage of oncologists plays a much more key role in the management of disease.

The article goes on to state: “ The relatively low number of practicing African American medical oncologists has implications for the oncology workforce and the delivery of quality cancer care. Overall, the supply of oncologists is not keeping

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Virgil Simons

## Patient Centricity and the Matrix of Expectations

The United States Institute of Medicine defines patient-centered care as: "Providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions<sup>1</sup>." While this definition seems readily clear, understandable, and actionable, the question remains as to why so many insufficiencies in the attainment of this goal exist. Have we really arrived to a point where patient-centricity is a fact or is it still a wished-for illusion? That neither one of the choices is the most definitive should not be a surprise because the reality of **Patient Centricity** depends, to a great extent, on perspective.

With the objective of Patient Centricity as the objective and desired goal, or the "**What**", then the delivery of that objective, best possible patient healthcare, becomes the "**How**". But as simplistic as this seems, the actuality is complicated by two very relevant factors – **Perspective** and **Expectations**.

In the ideal world of patient-centered care, the patient expects his/her clinical status to be reviewed collectively by physicians from each of the potential disciplines of therapeutic care and a collective decision taken, with the patient's input, as to the one with best outcomes therapeutically and quality of life. The patient expects that the recommendation would take into consideration his/her hoped-for disease-free survival and a close as possible normal life. Barring that, the patient should expect to

receive information from the physicians as to limitations to the patient expectations, based on disease stage, complicating clinical factors, etc. There should be the expectation of a clear dialogue as to the patient status, treatment options, potential side-effects, and a realistic projection as to the quality-of-life that could be attained.

Assuming the possibility of these expectations of the patient being met, it cannot be forgotten that the family often has expectations that may not in fact mirror those of the patient. In the face of terminal illness, will the family accept the patient's desires for quality-of-death versus the family's desire for using whatever measures may be available to possibly extend survival. Will the family push for extraordinary interventions to maintain an illusion of life versus allowing the natural progression of life? Will the family take on burdensome financial expenses in the belief that somehow survival can be purchased?

The expectations of centricity are not just on the side of the patient and family, but also with that of the physician as well. Does the doctor expect a better possible outcome if he/she uses just one more protocol or puts the patient into a clinical trial? Can the patient receive better care if referred to a more famous medical center/physician with access to a broader range of resources? Could the patient possibly be better served if they are put onto a different drug agent, which may not be covered by their current health insurance plan?

Further complicating the effectiveness, and efficacy, of the practitioner are the expectations of the healthcare system that employs them and its expectation for RBUs, in-hospital turnover, and physician financial productivity. Additionally we see the balance swinging away from subsidized government care for lower income patients to a model that seeks greater utilization by privately-insured patients, with the expectation for greater return-on-investment to the medical center. The Accountable Care Act in the U.S. seeks to address some of these issues by encouraging amalgamation of primary, and some specialty care, services into groups that should be able to deliver higher standards of

care at lower costs. Comparatively, we can look at the National Health Service of the UK where a more relevant incentive system is in place based on quantitative improvement in the patient's health.

Overriding this whole playing field is the perspective and expectations of the pharma industry. Pharma has the mission of developing products that will ultimately have positive benefits for the health of society, but this is not a charitable endeavor. New pharmaceutical developments have resulted in 14.5 million US cancer survivors alive as of January 2014. This number is expected to rise to 19 million by the year 2024<sup>2</sup>. Worldwide, in 2011, it was estimated that there were over 28 million people who had survived cancer within five years of diagnosis<sup>3</sup>. Further, it is estimated, based on 2012 data, that there will be approximately 14.1 million new cancer cases each year worldwide with increasing incidences of diagnosis and concomitant increases in the numbers of survivors<sup>4</sup>.

While we have seen pharma adopt seemingly relevant practices and management emphasis on the centrality of patients, is this a true reality? Mark Kessel recently wrote in an article in Nature Biotechnology: "... today's companies are measured on how well their stock performs and boards of directors incentivize management accordingly to meet Wall Street's demands. **The needs of patients are secondary.**" Pharma must begin to re-orient their management objectives, market execution, patient partnership engagements and standards of measurement if they want to continue to deliver superior value to patients and not just shareholders.

So we come down to the central question: "Whose reality is it anyway?" Anais Nin, famously said: "We do not see things as they are, we see things as we are." From all of the perspectives detailed above, we can see that there will be many, and possibly divergent, expectations as to healthcare delivery and to the reality of the centrality of the patient within the entire matrix. There will not be one answer or solution, but it should be a process of inclusion, a multidisciplinary dialogue as it were, of the myriad expectations that finally is in accord with

what the patient wants, needs, and can expect.

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*About the author: Virgil Simons is the founder and president of The Prostate Net, an international non-profit patient education and advocacy organization committed to providing credible and actionable information that will minimize the negative impact of prostate cancer. Using experience gained as a 19-year survivor of prostate cancer and a patient advocate, over the past 17 years he has built an organization that addresses disease risk awareness, early disease interdiction and advanced stage disease management.*

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pace with the increasing incidence of cancer diagnoses and prevalence of cancer survivors.”

This is important because of the complex nature of the relationship between doctor and patient in the management of advanced stage disease. The study results go on to say: “... a significant body of research in primary care and oncology settings has found that, compared with racially concordant clinic visits (i.e., both the patient and physician are the same race), communication in racially discordant clinic visits (i.e., an African American patient and a non-African American physician) is likely to be of poorer quality.

Specifically, patients in racially discordant clinic visits tend to ask fewer questions and are less likely to participate in decision making, whereas physicians in these visits tend to be less patient centered, more verbally dominant, and more contentious and to provide less information. Physicians and patients also demonstrate fewer expressions of positive affect and relationship-building attempts.”

As we have noted continually, the ability of the doctor and patient to achieve an effective working dialogue is essential to maximizing treatment decisions, therapeutic outcomes, and desired quality of life. The medical establishment is initiating changes to increase the recruitment of minority physicians as well as to sensitize practicing physicians to the cultural differences within minority communities. However, until the desired goal has been achieved, the burden of ensuring the best care possible will remain with the patients and their families.

**Source:** [http://jco.ascopubs.org/content/early/2015/09/17/JCO.2014.59.2493.full?cmpid=sk\\_jco\\_issuemark\\_earlyrel\\_all\\_10-05-15\\_read](http://jco.ascopubs.org/content/early/2015/09/17/JCO.2014.59.2493.full?cmpid=sk_jco_issuemark_earlyrel_all_10-05-15_read)

## USPSTF Recommendation Against Regular PSA Screening May Delay Diagnosis Of Prostate Cancer

The U.S. Preventive Services Task Force (USPSTF) recommendation against regular prostate specific antigen (PSA) screening for prostate cancer is controversial. While it may reduce the risk of over diagnosis and over treatment, the reduction in intermediate and high risk cancer diagnoses raises concern because of the potential for delayed diagnoses of important cancers in men who may benefit from treatment, according to investigators reporting in *The Journal of Urology*®.

Prostate cancer remains the second leading cause of cancer death among men in the U.S., with nearly 30,000 deaths annually. Deaths from prostate cancer have declined by about 40% since the advent of PSA screening in the late 1980s, and 40-70% of that decline may be attributable to screening. However, radiation therapy and surgery have a negative impact on quality of life. The uncertain benefit of PSA based screening, combined with the complications associated with treatment, led the USPSTF to conclude in October 2011 that the harms of PSA based screening outweighed the benefits, leading it to recommend against regular screening.

“Our study was designed to assess the impact of the USPSTF recommendation on screening practices among urologists and primary care providers and the incidence of prostate cancer,” explained lead investigator Daniel A. Barocas, MD, MPH, of the Department of Urologic Surgery, Vanderbilt University Medical Center, Nashville, Tennessee. “We know there is decreased utilization of PSA testing in some institutions and health systems, but has the number of incident cases per month changed substantially since the draft guideline was issued?”



Investigators evaluated the effect of the USPSTF guideline on the number and distribution of new prostate cancer diagnoses in the U.S. They identified incident cancers diagnosed between January 2010 and December 2012 in the National Cancer Database and assessed the trend of new prostate cancers diagnosed each month before and after the draft guideline was issued, comparing their findings with colon cancer.

This study helped quantify the potential benefits (reduced harms of over diagnosis and over treatment of low risk disease and disease found in elderly men) and potential harms (missed opportunities to diagnose important cancers in men who may benefit from treatment).

The number of prostate cancer diagnoses dropped by more than 12% (1363 cases) in the month after the USPSTF draft guideline was issued and the number continued to drop, resulting in an overall decline of 28% in incident prostate cancer diagnoses in the year after the draft guideline was issued. By contrast, the number of monthly colon cancer diagnoses remained stable. Diagnoses of low, intermediate, and high risk prostate cancers all decreased significantly, but new diagnoses of non-localized disease did not change. The decreases were similar across all subgroups of age, comorbidity, race, income, and insurance.

The study showed that 12 months after the draft guidelines were published diagnoses of new low risk cancers had fallen by 37.9%, and continued to fall more rapidly than other disease risk strata, suggesting that, in this regard, the USPSTF recommendation had its intended effect,. Similarly, new diagnoses had fallen by 23.0-29.3% among men over age 70 and by 26.0%

among infirm men, populations at risk for harms of treatment but unlikely to live long enough to benefit from early detection.

However, the study also identified a drop of 28.1% in diagnoses of intermediate risk disease and 23.1% in high risk prostate cancer one year after the draft guideline, which could result in missing important opportunities to spare men with higher risk cancers from progressive disease and cancer death.

“While some of the effects of this guideline may be beneficial in terms of reducing harms of over diagnosis and over treatment, the reduction in intermediate and high risk cancer diagnoses raises concern for delayed diagnoses of important cancers associated with inferior cancer outcomes,” noted Dr. Barocas. “Future research should focus on prostate cancer screening paradigms that both minimize harms and maximize the potential benefits of screening, as well as accounting for individual patient risk factors and preferences.”

Source: <http://www.news-medical.net/news/20150922/USPSTF-recommendation-against-regular-PSA-screening-may-delay-diagnosis-of-prostate-cancer.aspx>



## Gleason 6: Safety in the Number?

The lexicon of terms in prostate cancer emphasizes the Gleason Score as a gold standard in diagnosing the disease. The National Cancer Institute defines it as: *A system of grading prostate cancer tissue based on how it looks under a microscope. Gleason scores range from 2 to 10 and indicate how likely it is that a tumor will spread. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread; a high Gleason score means the cancer tissue is very different from normal and the tumor is more likely to spread.*

Using this guideline, physicians have felt that a Gleason score of 6 was a clear indicator that any therapeutic approach would be good for the patient; and it was also a strong element in supporting a course of active surveillance.

However, recent research has shown that it may not be the safe and certain factor thought to be. Though the U.S. Food and Drug Administration (FDA) stated that based on the REDUCE and PCPT clinical trials “Decreased detection of Gleason  $\leq 6$  cancers is not worthwhile, 80% are insignificant”, data reported at a recent European conference showed:

- 25 to 45% of Gleason 6 prostate cancers are undergraded
- Standard biopsy assessments miss significant proportions of aggressive disease:
  - 25 to 50% upgrade to Gleason 7
  - < 10% upgrading to Gleason  $\geq 8$
  - 10 to 25% upstaging to extra-capsular disease
  - < 3% positive lymph nodes

So, while current thinking is that a Gleason 6 cancer is an indolent disease with limited impact on mortality, the reality is that it can progress over time into a lethal stage.

Obviously, in order to reduce the uncertainty in the diagnosis, we need better diagnostic/prognostic tools like a better understanding of the parameters of PSA and newer biomarkers. But we should encourage evaluation and utilization of different techniques of disease engagement:

- Do not assume that the presence of disease is “insignificant”
- Take major efforts to exclude the possibility of more aggressive disease
- Utilize risk calculators to better stratify risk of progression
- Utilize advance imaging techniques, such as parametric MRI, to better diagnose the disease
- Consider active surveillance as an important therapeutic option

A countervailing view on the subject is that in too many cases we have seen a Gleason 6 cancer become the subject of over treatment, resulting in unnecessary protocols for a disease that may never have progressed. Yet, we need to strike a balance. Dr. H. Ballentine Carter and others from Johns Hopkins have weighed in on the subject; their comments can be seen at: <http://jco.ascopubs.org/content/30/35/4294.full>

Bottom-line, as always, we counsel the patient and his family to become their own best advocates that can ensure receiving the proper counseling/treatment; reduce the risk of over treatment and its associated harms; and gain the desired outcome and quality of life.

# Medical News

## MEN WHO USE FINASTERIDE TO TREAT BENIGN PROSTATE ENLARGEMENT EXPERIENCE WORSENING ED

Men with benign prostate enlargement who used finasteride (also known as Proscar and Propecia) to treat their condition, experienced worsening erectile dysfunction (ED) that did not resolve with continued treatment. In addition, they experienced a reduction in their testosterone levels leading to hypogonadism (little to no production of sex hormones). However, men who used Tamsulosin (Flomax) experienced none of these adverse side effects.

According to the researchers both of these drugs have been proven useful in treatment of lower urinary tract symptoms related to BPH. "However, 5 reductase inhibitors exert undesirable sexual side effects and, in some cases, these effects are persistent," explained corresponding author Abdulmaged M. Traish, MBA, PhD, professor of biochemistry and urology at BUSM. "Since sexual function is considered an integral part of overall health, it is important that physicians are aware of the adverse side effects of this class of drugs on human health in general and on sexual function in particular. Our study emphasized that the effect on erectile function is a serious concern and needs to be considered more carefully."

The findings, currently available online in the journal *Hormone Molecular Biology and Clinical Investigation*, were led by researcher from Boston University School of Medicine (BUSM).

**Source:** [News-medical.net](http://News-medical.net)

## STUDY SHOWS 28% DECLINE IN PROSTATE CANCER DIAGNOSES FOLLOWING USPSTF RECOMMENDATION AGAINST PSA TESTING

A new study led by Vanderbilt University Medical Center investigators found new diagnoses of prostate cancer in the U.S. declined 28 percent in the year following the draft recommendation from the United States Preventive Services Task Force (USPSTF) against routine PSA screening for men. The new research, led by first author Daniel Barocas, M.D., MPH, assistant professor of urological surgery and medicine, was posted online in the June 15 issue of *The Journal of Urology* in advance of publication.

In October 2011, the USPSTF issued a draft guideline discouraging the use of prostate-specific antigen (PSA)-based screenings for prostate cancer after concluding the harms outweigh potential benefits. Harmful side effects of treatment may include incontinence, erectile dysfunction and radiation cystitis.

The research revealed that 12 months after the draft USPSTF guidelines were published diagnoses of new low-risk cancers had fallen by 37.9 percent while colon cancer cases remained stable.

New prostate cancer diagnoses also declined by 23 to 29.3 percent among men over age 70 and 26 percent among men considered infirm. The authors note these are populations who are unlikely to live long enough to benefit from early detection and are at risk of harms of treatment.

'These findings suggest that reduced screening may result in missed opportunities to spare these men from progressive disease and cancer death,' said Barocas.

**Source:** [News-medical.net](http://News-medical.net)

## INTERNATIONAL STUDY PROVIDES EVIDENCE OF CLEAR LINK BETWEEN SMOKING AND RISK OF PROSTATE CANCER

Smoking is a known risk factor for the development of various forms of cancer. However, when it comes to the link between smoking and prostate cancer, the findings of previous studies have been contradictory. Now, for the first time, an international study led by MedUni Vienna and Basle University Hospital, has provided evidence of a clear link.

The study, which was recently published in "European Urology", the world's leading journal in the field of urology and nephrology, shows that, following removal of the prostate gland due to prostate cancer, smokers and ex-smokers have a much higher risk (specifically twice the risk) of recurrence of prostate cancer (biochemical recurrence; BCR).

"Our study findings underline the importance of informing a prostate cancer patient about the negative effects of smoking," says Shahrokh F. Shariat, Principal of the University Clinic of Urology at MedUni Vienna, who set up the ground-breaking study together with Malte Rieken, University Clinic of Urology at Basle University Hospital.

It makes sense for prostate cancer patients to quit smoking.

Source: [News-medical.net](http://News-medical.net)



## PSMA CAN BE AN IDEAL TARGET FOR DIAGNOSIS AND TREATMENT OF PROSTATE CANCER

Prostate-specific membrane antigen (PSMA) is a surface protein that is normally present on healthy prostate cells, but is found at much higher levels on prostate cancer cells. It is barely found in the rest of the body. "Therefore, PSMA is an ideal target for diagnostic purposes as well as targeted therapies against prostate cancer," says biotechnologist Dr. Matthias Eder of the German Cancer Research Center (Deutsches Krebsforschungszentrum, DKFZ).

At Heidelberg University Hospital, a team led by nuclear medicine specialist Prof. Dr. Uwe Haberkorn has already used radioactively labeled PSMA-617 to treat individual patients with advanced prostate cancer. The physicians made use of the therapeutic nuclides lutetium-177 and actinium-225. After treatment with the lutetium-labeled radiopharmaceutical, levels of the prostate cancer marker PSA fell sharply in 70 percent of cases; after treatment with the actinium-labeled radiopharmaceutical, this effect was observed in all patients.

Source: [News-medical.net](http://News-medical.net)

## NEW GENOMIC FINGERPRINT MAY PREDICT PROSTATE CANCER RISK IN AFRICAN AMERICAN MEN

African American men are more likely to develop prostate cancer than European American men, and are also more than twice as likely to die from it. Although there are many reasons that contribute to this health disparity, new research shows that African American men may have a distinctly different type of prostate cancer than European American men, according to new genomic fingerprinting results.

They found a subtype that the researchers coined "triple negative prostate cancer," defined as the



## TESTOSTERONE THERAPY NOT ASSOCIATED WITH INCREASED RISK OF AGGRESSIVE PROSTATE CANCER

A new population-based study from The University of Texas Medical Branch at Galveston showed for the first time that exposure to testosterone therapy over a five-year period was not associated with an increased risk of aggressive prostate cancer. Further, risk of high-grade prostate cancer did not increase according to the total number of testosterone injections.

Given the slow growth of prostate cancer development, this investigation offers novel and important information to physicians, patients and the general public," said lead author Jacques Baillargeon, UTMB professor of epidemiology in the department of preventative medicine and community health. "This study's findings offer important information regarding the risk-benefit assessment for men with testosterone deficiency who are considering treatment."

**Source:** [News-medical.net](http://News-medical.net)

## FEWER, HIGHER DOSES OF RADIOTHERAPY EFFECTIVE AT TREATING PROSTATE CANCER

Giving fewer but higher doses of radiotherapy, is as effective at treating prostate cancer as giving lower doses for a longer period, according to new research presented at the 2015 European Cancer Congress.

Some short-term side effects of the higher daily radiotherapy doses during and immediately after radiotherapy were higher than for standard radiotherapy, but these - including bowel and bladder problems - were not long-lasting. There was no difference in the side effects after six months or during the next five years.

Professor Malcolm Mason, Cancer Research UK's prostate cancer expert, said: "These results are great news for men. From a logistical and patient convenience point of view, being able to treat patients over a shorter period of time has been a goal for specialists, but the question has always been whether it was safe to do so. This study shows that it is safe and effective, and there should be no reason why this cannot be implemented immediately - it is saving the NHS resources.

**Source:** [News-medical.net](http://News-medical.net)



The Prostate Net® is a non-profit patient education and advocacy organization founded 18 years ago by Virgil Simons, a 20-year survivor of prostate cancer and a patient advocate. The Prostate Net has become an international organization that uses a matrix of informational techniques to address disease risk awareness and early disease interdiction.

## The core objective of The Prostate Net’s mission is to:

1. Educate consumers most at-risk from a diagnosis of prostate cancer
2. Inform the community on other diseases and conditions of negative impact
3. Motivate consumers to make informed choices as to healthcare and lifestyle management
4. Provide on-going health care interaction between patient and professional communities
5. Create an interactive network to maximize actionable healthcare messages

The strength of The Prostate Net’s mission is aided by organizations with which we are associated: American Society of Clinical Oncology, Department of Defense Prostate Cancer Research Program, American Association for Cancer Research and European Association of Urology among others.

## Our active initiatives include, but are not limited to:

### Education:

- Patient and professional Website - [www.theprostatenet.org](http://www.theprostatenet.org)
- Spanish language site - <http://theprostatenet.org/espanol/>
- Educational Symposia - <http://theprostatenet.org/Symposium.html>

### Research:

- Continuing partnerships with university based community studies
- Consulting relationships to local government agencies; materials for patient education/recruitment; training of agency staff, etc.

### Community Interventions:

- Gentlemen, Check Your Engines™, focuses on Men’s & Women’s health issues featuring on-site health education and testing - <http://theprostatenet.org/programs.html>

Through the 17 years of our existence we have expanded our reach throughout the U.S. and to more than 50 countries. Our overarching objective is to continue to provide service to an expanding range of consumer, healthcare, government, university and service agencies to aid in reducing health disparity through education, research and community intervention. We inform to fight.

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