

*In The*

# Know

Confronting Prostate Cancer

October 2014



The United States Institute of Medicine defines Patient Centricity 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.

But, in this world of emerging and expanding reliance on technology in healthcare, how will doctors stay engaged with their patients to insure that the stated preferences, needs, and values are ensured?

More critically, how will patients and their families navigate their way through the process to ensure that they are receiving the healthcare that they want and not what the technology suggests?

We will review these concepts and concerns in this issue.

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## EDITORIAL



*As more and more technological developments are introduced to diagnose and manage conditions, are their costs to healthcare systems outweighing the benefits they bring? Patients are increasingly the focus for new products and services, but not always for the right reasons, argues Virgil Simons of The Prostate Net.*

Virgil Simons

Last year, in the US alone, more than \$11.9 billion was spent on prostate cancer diagnostics, procedures and therapeutics and, because of an aging population, that number is expected to increase in the future.

Part of that expense is being driven by many new drugs for treatment of advanced-stage disease that can cost more than \$100,000 per treatment, as well as increasing costs for conventional radiation and surgery, augmented by new mechanistic protocols.

Additionally there has been an explosion, particularly in Europe, of new imaging tools such as CT scans, PET scans, multi-parametric MRI and other nuclear medicine procedures. Coupled with this there has been an increase in the use of various diagnostic and prognostic tests based on genetic variants, all of which will significantly add to the cost of standard of care.

Further, the expansion in diverse technological services and tools has the potential to complement traditional physician-delivered care, but possibly at the expense of increased complexity of understanding and incremental cost.

These elements are not confined to the US or Europe; the entry of these new protocols into the armamentarium of a country's medical system will have an impact on healthcare expenditures, be they in the government or private sectors.

Definitely the patient is becoming more of a 'centric' presence, but is it as a recipient of better, more personalized service, or as a marketing objective for targeted products and services with questionable positive impact on their care, therapeutic outcomes, and quality of life?

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.'

That is a noble concept, but the execution diverges quickly. In the last two months I have been contacted by third-party companies who wanted to 'survey' my database of patients and families to 'gain their perspectives on certain types of treatments, etc.' Their business plan was to compile the information gathered and then sell it to drug companies, insurance providers and other healthcare suppliers. In return, they offered a share of their revenues to my organization. We declined the offer because, while technically legal, it gave a sense of being wholly unethical.

Into this milieu of 'personalized services,' we see entrants ranging from Health Tap, offering concierge online consultations for \$99/month, to the Cleveland Clinic offering online second-opinion services ranging from \$565 to \$745 per incident.

Medical apps are proliferating everywhere to the point where recently both the UK's NHS and the National Library of Medicine in the US have made recommendations as to the most 'clinically safe' ones for patients' use.

At some point in the not too distant future we will consult with our doctors, or other physicians, on any electronic device; receive prescriptions, referrals, or reminders for our compliance assistance, as well as share our medical records and/or obtain diagnostic evaluations from service providers thousands of miles away.

But is this new world really going to provide an enhanced level of care? Is it expanding the capability of the doctor to better care for the patients? Is it all really necessary?

Apart from driving the overall expenditures for care even higher, we are also fomenting a new digital divide in healthcare based on who can access the technology and who can afford it. I have a high degree of certainty that implementation of all these protocols will have little impact on reducing healthcare disparities related to racial and socio-economic factors.

If we accept that healthcare must be a sustainable and equitable right for the people in our societies, how do we achieve that objective in an environment more complex, more economically hierarchical, and more expensive overall?

This is the central question in the matrix of patient-centricity that has, as yet, failed to be addressed.

## African American Men With Very Low-Risk Prostate Cancer Exhibit Adverse Oncologic Outcomes After Radical Prostatectomy: Should Active Surveillance Still Be an Option for Them?

Active surveillance (AS) is a treatment option for men with very low-risk prostate cancer (PCa); however, favorable outcomes achieved for men in AS are based on population studies that under-represent African American (AA) men. This study was designed to explore whether race-based health disparities exist among men with very low-risk PCa. The authors evaluated oncologic outcomes of AA men with very low-risk PCa who were candidates for AS, but elected to undergo radical prostatectomy (RP).

The study found that AA men with very low-risk PCa, who meet criteria for AS but undergo immediate surgery, experience significantly higher rates of upgrading (increase in Gleason score) and adverse pathology (positive surgical margins; higher Cancer of the Prostate Risk Assessment Post-Surgical scoring system (CAPRA-S) scores) than do white men and men of other races. AA men with very low-risk PCa should be counseled about increased oncologic risk when deciding among their disease management options.

A complicating factor has been the downstream effect of the recommendation by the U.S. Preventive Services Task Force (USPSTF) to de-emphasize PSA screening. While indolent disease, which does not necessarily require treatment, remains relatively common, the inability of medical professionals to properly clinically stage prostate cancer and to correctly estimate the biological aggressiveness of the disease has resulted in men being treated when there is little benefit to be gained.

In the future a better understanding of the biology of low-risk Pca and effective education of the potential patient population as to treatment choice will achieve the goal of providing the right care to the right patient at the right time.

- Source: <http://jco.ascopubs.org/content/early/2013/06/17/JCO.2012.47.0302.abstract>
- Source: <http://www.cancernetwork.com/oncology-journal/active-surveillance-african-american-men-prostate-cancer-course>

## Looking For a Clinical Trial?

More and more, patients are seeing the participation in clinical research trials can often be an avenue for better and more appropriate treatment, extended survival, and an improved quality of life. But, the problem they confront is how to find the right trial from the many thousands that currently exist.

Online clinical trial matching services can often be of assistance. Here is a listing of some of the available matching services:

**ClinicalTrials.gov** - <https://www.clinicaltrials.gov>

**Center for Information and Study on Clinical Research Participation (CISCRP)** - <https://www.ciscrp.org>

**CancerTrialsHelp.org** - <http://www.cancertrialshelp.org>

**CenterWatch** - <http://www.centerwatch.com/health-resources/>

**EmergingMed** - <https://www.emergingmed.com>

**MyClinicalTrialLocator.com** - <http://myclinicaltriallocator.com>

**TrialReach** - <https://trialreach.com>

Email us at:  
[support@prostatenet.org](mailto:support@prostatenet.org)

Mailing address:  
P.O. Box 10188#77550  
Newark, NJ 07101-3188

[www.prostatenet.org](http://www.prostatenet.org)

The   
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Net

## Prostate Cancer Risk Calculator Offers Men ‘Individual Risk Assessment’

Men worried about prostate cancer have a new online resource, freely available, to help them assess their risk. The multi-step Prostate Cancer Risk Calculator\*, (launched 17 May 2012), has been created by the founders of the European Randomized Study of Screening for Prostate Cancer (ERSPC).

Prostate cancer is one of the most common cancers in men but recent improvements in treatment and diagnosis mean that more men will survive the disease. The online resource provides a range of helpful information about the disease. This includes the benefits and disadvantages of going for a PSA test when you do not have symptoms. PSA levels tend to increase as men age and can be a sign of prostate disease, though not always cancer.

Men can use the first two calculators to assess their individual risk of developing prostate cancer without needing any medical expertise. Five risk calculators have been created for clinicians to use as part of their clinical practice.

All of the calculators are based on robust evidence gained from research carried out by the world’s largest study into screening for prostate cancer, the European Randomized Study of Screening for Prostate Cancer (ERSPC).

Dr. Monique Roobol, associate professor at Erasmus Medical Center, Rotterdam, and one of the creators of the Prostate Cancer Risk Calculator, said: “Our seven prostate cancer risk calculators help to build up a picture which enables a clinician to predict the presence of cancer before a biopsy is taken. The first two calculators are designed to help men take the first steps in assessing their risk.” If cancer is indicated, the risk assessment then helps decide if it is potentially aggressive and life threatening or if it is safe to treat it conservatively.

Access to the Risk Calculators can be gained through: [www.prostatecancer-riskcalculator.com](http://www.prostatecancer-riskcalculator.com).

• **Source:** [http://www.europeanurology.com/article/S0302-2838\(12\)00834-2/fulltext/a-calculator-for-prostate-cancer-risk-4-years-after-an-initially-negative-screen-findings-from-erspc-rotterdam](http://www.europeanurology.com/article/S0302-2838(12)00834-2/fulltext/a-calculator-for-prostate-cancer-risk-4-years-after-an-initially-negative-screen-findings-from-erspc-rotterdam)

## An Emerging Voice for The Prostate Net



Radio continues to be a vehicle for delivering information in an immediate environment. Following on that trend The Prostate Net has launched a radio network based in Barcelona, Spain that delivers English-language broadcasts daily to international audiences via FM radio and streaming online.

<http://yourlisten.com/theprostatenet/discussion-about-new-technology-in-healthcare>

<http://yourlisten.com/EnglishRadio/dr-adam-dicker-and-dr-joan-carles-talk-about-cancer>

<http://yourlisten.com/theprostatenet/poverty-healthcare-womens-rights>

<http://yourlisten.com/theprostatenet/healthy-living-with-juiceplus>

<http://yourlisten.com/theprostatenet/african-immigrant-lives-in-barcelona>

<http://yourlisten.com/theprostatenet/dental-hygiene-and-your-health>

106.9FM in Barcelona on Thursdays from 10:00 to 11:00 AM (CET – or 4:00 to 5:00 AM EDT)

**Live streaming at:** <http://radiokanalbarcelona.com>

**Or listen to our podcasts at:**

- <http://yourlisten.com/theprostatenet>
- <http://yourlisten.com/EnglishRadio>

## Medical News from International Sources

### Immediate Versus Deferred Initiation Of Androgen Deprivation Therapy In Prostate Cancer Patients With PSA-Only Relapse.

The optimal timing to start androgen deprivation therapy (ADT) in prostate cancer patients with rising prostate-specific antigen (PSA) as the only sign of relapse is unknown.

The initiation of ADT is associated with a decrease in quality of life, increased risk of metabolic syndrome and associated cardiovascular risk plus the development of osteoporosis and the loss of cognitive function.

The conclusion of the study suggests that prostate cancer patients undergoing immediate ADT initiation within three months after PSA-only relapse had similar survival to those who deferred ADT initiation within 3 months after clinical progression.

- Source: <http://www.sciencedirect.com/science/article/pii/S0959804915002191>

### Is Thulium Just Another Laser For Prostatectomy?

In 1995 we saw the first wide-scale use of lasers in the surgical management of benign prostatic obstruction. Since then we have seen it become a very popular treatment worldwide, fueled by factors of less morbidity (increased disease state or symptoms), better hemostatic (lower blood loss) properties, and the ability of the surgeon to utilize more active anticoagulation (prevention of blood clots) agents.

Currently, Holmium and Greenlight lasers are the most commonly used laser treatments. However, in 2005 we saw the introduction of the Thulium laser into urological practices. Compared to pulsed lasers, Thulium delivers energy in a continuous wave fashion producing a clean and fast tissue cutting. It can both cut and ablate (vaporize) tissue similar to Holmium but it can also vaporize tissue very effectively, similar to the Greenlight laser.

Based on increasingly widespread use, Thulium should be expected to play a major role in laser prostatectomy because it combines the advantages of all alternative lasers into a single treatment unit.

- Source: [https://www.webmedcentral.com/article\\_view/2526](https://www.webmedcentral.com/article_view/2526)

### Study: da Vinci Complications May Be “Vastly Underreported”

Adverse events associated with Intuitive Surgical's da Vinci robot have been “vastly underreported,” according to Johns Hopkins researchers who culled news reports and court records to identify unreported complications associated with the surgical system.

According to the study, published in the Journal for Healthcare Quality, thousands of mishaps related to the robotic surgical equipment were reported to FDA between 2000 and 2012. Most of those events did not cause patients harm; 71 of the mishaps resulted in death, and another 174 caused a patient injury.

However, news reports and court documents identified botched operations that were not reported to FDA, according to the study. The findings suggest that many cases of complications associated with the robot may not be reported to the agency.

Nonetheless, use of the robot has risen dramatically across the United States; the number of procedures performed using da Vinci has increased by more than 400% from 2007 to 2011. This expansion has occurred without proper evaluation and monitoring of the benefits, says lead study author Martin Makary.

“This whole issue is symbolic of a larger problem in American health care, which is the lack of proper evaluation of what we do,” he says, adding, “We adopt expensive new technologies, but we don't even know what we're getting for our money—if it's of good value or harmful.”

- Source: <https://www.advisory.com/daily-briefing/2013/09/10/study-da-vinci-complications-may-be-vastly-underreported>

- Source: <http://onlinelibrary.wiley.com/doi/10.1111/jhq.12036/abstract>

## Hospitalization Costs For Radical Prostatectomy Attributable To Robotic Surgery

With health technology innovation responsible for higher health care costs, it is essential to have accurate estimates regarding the differential costs between robot-assisted radical prostatectomy (RARP) and open radical prostatectomy (ORP).

Robot-assisted laparoscopic prostatectomy is increasingly being used compared with the standard open technique, but it remains uncertain whether potential benefits offset higher costs.

The da Vinci robotic surgery system—which typically costs between \$1.5 million and \$2.5 million and is used in more than 1,400 hospitals nationwide—allows surgeons to perform procedures using hand controls at a computer system several feet away from the patient. It has been on the market for more than a decade, and more than one million procedures have been performed using the robot.

While there have been many claims as to clinical effectiveness of the robot versus the open procedure, there have not been any studies directly comparing the long term benefit. What is certain is that the cost of a robotic procedure will be on average \$1,547 to \$2,542 higher than the comparable open system.

Actual fully transparent cost comparisons are still difficult to determine, confounded by lack of claims and reimbursement data, particularly for private insurance, and on hospital amortization rates for the computer system. Ongoing study is warranted to determine if a true health benefit is being delivered.

- **Source:** <http://www.ncbi.nlm.nih.gov/pubmed/22959352>
- **Source:** <https://www.advisory.com/daily-briefing/2013/09/10/study-da-vinci-complications-may-be-vastly-underreported>
- **Source:** <http://www.ncbi.nlm.nih.gov/pubmed/23498062>

## 'Unprecedented' Survival Benefit in Prostate Cancer With Addition of Docetaxel to Hormone Therapy

Adding docetaxel to standard androgen ablation therapy (i.e., testosterone suppression) extended survival by more than 1 year in men with newly diagnosed metastatic hormone-sensitive prostate cancer in the phase III E3805 trial, funded by the National Institutes of Health. As reported at the ASCO Annual Meeting in Chicago, the survival benefit was observed mainly in men with more extensive metastatic disease.

ASCO Immediate Past President Clifford A. Hudis, MD, FACP, called these results achieved with an older drug “unprecedented” and “transformative.”

“This is the first study to identify a strategy that prolongs survival in newly diagnosed metastatic prostate cancer. The benefit is substantial and warrants this being adopted as a new standard treatment for men who have high-extent disease and are able to tolerate chemotherapy,” said lead author Christopher J. Sweeney, MBBS, medical oncologist at the Lank Center of Genitourinary Oncology at the Dana-Farber Cancer Institute in Boston.

Looking at the data in greater depth, most of the survival benefit was observed in men with extensive disease—either a high burden of bone metastases or liver or lung metastases. In patients with low-volume disease, median overall survival has not yet been reached in either arm. Dr. Sweeney said that longer follow-up is needed to get more certainty on the benefit of docetaxel added to androgen-deprivation therapy in patients with low-volume metastatic disease.

- **Source:** <http://www.ascopost.com/issues/june-10,-2014/unprecedented-survival-benefit-in-prostate-cancer-with-addition-of-docetaxel-to-hormone-therapy.aspx>

## High PSA Anxiety, Low Health Literacy Associated with Salvage ADT Choice

Men with prostate cancer who experience PSA recurrence after radiotherapy are twice as likely to undergo salvage androgen deprivation therapy (ADT) if they have high PSA anxiety or low health literacy compared to those who don't.

The findings, published in *Annals of Oncology*, suggest that many of these men receive higher rates of unproven treatment. In addition, men with higher levels of health literacy were almost half as likely to undergo salvage ADT compared to those with low levels of health literacy in univariable analysis.

“Given that early salvage ADT is costly, worsens quality of life, and has not been shown to improve survival, quality improvement strategies are needed for these individuals,” the authors concluded.

- **Source:** [http://www.researchgate.net/publication/275667517\\_High\\_PSA\\_anxiety\\_and\\_Low\\_health\\_literacy\\_skills\\_drivers\\_of\\_early\\_use\\_of\\_salvage\\_ADT\\_among\\_men\\_with\\_biochemically\\_recurrent\\_prostate\\_cancer\\_after\\_radiotherapy](http://www.researchgate.net/publication/275667517_High_PSA_anxiety_and_Low_health_literacy_skills_drivers_of_early_use_of_salvage_ADT_among_men_with_biochemically_recurrent_prostate_cancer_after_radiotherapy)

### Pre-Chemotherapy Indication For Xtandi In Prostate Cancer

The US FDA has approved the use of the oncology drug Xtandi prior to chemotherapy in patients with advanced prostate cancer.

Xtandi (enzalutamide), an oral once-daily drug developed by Astellas and its partner Medivation, is now available in the US to treat men with metastatic castration-resistant prostate cancer (CRPC) who have not received previous treatment. This expands its existing indication, which restricted the drug’s use to men who had previously been treated with a form of chemotherapy known as docetaxel.

Dr. Tomasz Beer, co-principal investigator of the PREVAIL study added: “Furthermore, in the PREVAIL trial, the median time to initiating chemotherapy was delayed by 17 months with enzalutamide treatment as compared to placebo, so the result is a meaningful period of time during which men have their disease controlled without the need for chemotherapy.”

- **Source:** [http://www.pmlive.com/pharma\\_news/prechemotherapy\\_indication\\_for\\_xtandi\\_in\\_prostate\\_cancer\\_598537?SQ\\_DESIGN\\_NAME=2&](http://www.pmlive.com/pharma_news/prechemotherapy_indication_for_xtandi_in_prostate_cancer_598537?SQ_DESIGN_NAME=2&)
- <http://www.curetoday.com/publications/cure/2014/winter2014/fda-approves-new-uses-for-existing-cancer-treatments>



### New Radiation Therapy Prolongs Prostate Cancer Survival

A new radiation therapy can extend the lives of men with the most advanced form of prostate cancer, a large new study has found. The study, published in *The New England Journal of Medicine*, involved a large group of men with late-stage prostate cancer who were expected to live less than a year.

The treatment is an isotope of radium that zeroes in on cancer cells that have spread to bones. The drug was approved by the Food and Drug Administration in May and is sold under the brand name Xofigo.

Those who were given the drug saw their median survival time increase to nearly 15 months, a “substantial 30 percent improvement,” said Dr. Chris Parker, the lead author of the new study and a consultant clinical oncologist at the Royal Marsden Hospital and the Institute of Cancer Research, both in London.

The new drug contains radium 223, which targets bone and emits alpha particles that are far more massive and energetic than the beta particles emitted by older radioimmunotherapies like strontium. Once in the bone, the heavier alpha particles do not stray as far as the lighter beta particles, which makes them less toxic to bone marrow, Dr. Parker said. “If the drug were used earlier and the 30 percent benefit maintained,” he said, “it would give a longer absolute benefit.”

**Source:** <http://www.curetoday.com/publications/cure/2014/winter2014/fda-approves-new-uses-for-existing-cancer-treatments>

The Prostate Net® is a non-profit patient education and advocacy organization founded 17 years ago by Virgil Simons, a 19-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.

*The “In The Know” newsletter is partially supported by an unrestricted educational grant from TEVA Pharmaceuticals, Millennium: The Takada Oncology Company and Astellas Pharmaceuticals.*

