Prostate Cancer, to Screen or Not to Screen: What a Stupid Question or How the USPSTF Got it all Wrong

Spring 2013

“The U.S. Preventive Services Task Force (USPSTF) recommends against prostate-specific antigen (PSA)-based screening for prostate cancer (D recommendation: not recommended; harm outweighs benefits or no net benefit).” May 2012. The screening, diagnosis and treatment of prostate cancer remain a confusing and confounding dilemma for the patient (and some physicians). A recent recommendation by the U.S. Preventive Services Task Force (USPSTF) to recommend against screening for prostate cancer only compounds the uncertainty of what is a patient to do? First, let me briefly review the rationale for screening. While certainly not perfect, PSA (prostatic specific antigen) is an excellent screening tool. There will always be false positives and false negatives. This means that a patient with a normal PSA may have prostate cancer, and conversely, an elevated PSA can occur without cancer being present. However, there is currently no better test available that can so easily be used to screen for prostate cancer.

In comparison to the blood PSA level, PSA velocity is a more sensitive indicator for the presence of prostate cancer. An individual’s PSA should not increase greater than 0.5-0.75 annually. Other non cancerous conditions can cause an abnormal PSA test, such as an inflammation or infection of the prostate, or an enlarged prostate (benign prostatic
hypertrophy or BPH). To help discern a benign from a possible malignant condition, other tests, such as a digital rectal exam (DRE), prostate ultrasound, and urinary PCA3-D can aid the urologist in the decision process. Finally, about 15% of the patients are diagnosed by an abnormal digital rectal exam despite a normal PSA or PSA velocity.

Why does this matter at all? In the United States, prostate cancer remains the most common cancer in men, and the 2nd leading cause of cancer death, so this disease has a significant impact upon the male and related population. In my 30 years in urology, I have witnessed, first hand, the impact of PSA screening on prostate cancer. Initially, PSA was used to follow the progression of prostate cancer. Interestingly enough, several of my patients began to ask, “Why can’t PSA be used to screen for prostate cancer?” Well, they had more common sense and better vision than I, but it was not until Dr. William Catalona’s landmark study on the benefits of PSA for screening, that there was a dramatic change in the ability to diagnose prostate cancer in its early stages. Until that time, DRE was the only way to diagnose prostate cancer, and the incidence of larger volume cancer and tumor spread (metastasis) was much higher than today, and more of my patients were incurable and dying of metastatic prostate cancer. Today, generally, the only patients that I see with locally advanced or metastatic disease are those who were not on an annual PSA screening program. According to a recent article by Patrick Walsh MD, prior to PSA testing, 20% of newly diagnosed prostate cancer was already spread to other parts of the body (metastasized), and currently, it is only 4%. Therefore, we are currently diagnosing prostate cancer when there is smaller tumor volume, with greater chance of cure. Dr. Walsh also noted that between 1994 and 2004, prostate cancer deaths decreased by 40%, which is consistent with the 5 year cancer survival statistics published by
the American Cancer Society. Furthermore, a recent study from the European Randomized Study of Screening for Prostate Cancer (ERSPC) demonstrated that patients who were screened had a 30% reduction in the relative risk of metastatic prostate cancer compared to the control group of men who were not screened.

The major dilemma facing PSA screening is whether or not the cancer needs to be treated. That is because not all prostate cancer is the same, and some will remain indolent while other cancer is more aggressive and will continue to grow and spread if left untreated. The problem is can we tell which form does each patient have? We are making some progress with this issue and molecular pathology offers some hope that in the future, we will be able to determine which patient requires treatment. Therefore, diagnosis does not always mean complete surgical removal or ablation of the gland. Active surveillance (watchful waiting) and focal therapy with cryosurgery, high intensity focused ultrasound and possibly interstitial laser are all alternatives in small volume, low grade prostate cancer. Focal therapy allows us to treat the cancer and avoid the potential complications that could occur with surgical removal or total gland ablation with radiation, high intensity focused ultrasound or cryosurgery. Active surveillance avoids all of the potential side effects of any therapy.

Who are the members of US Preventative Services Task Force?

Currently the USPSTF consists of 16 members [volunteers], most of whom are MD’s with M.P.H. or PhD with degrees, 2 nurses with R.N. and other advanced degrees and one Ph.D. Of this group, 3 are trained in pediatrics, 3 are in family medicine, 4 are in internal medicine, 1 is in geriatrics, and 2 are in
obstetrics and gynecology. There is no representation from urology or general surgery, and I am not sure how many members have a clinical practice, and actually see and treat patients on a regular basis.

“Prostate cancer is a serious health problem that affects thousands of men and their families. But before getting a PSA test, all men deserve to know what the science tells us about PSA screening: there is a very small potential benefit and significant potential harms. We encourage clinicians to consider this evidence and not screen their patients with a PSA test unless the individual being screened understands what is known about PSA screening and makes the personal decision that even a small possibility of benefit outweighs the known risk of harms.”
—USPSTF Co-Chair Michael LeFevre, M.D., M.S.P.H. May 22, 2012

How did the USPSTF get it so wrong? In my opinion, there are multiple factors that led the task force to the wrong conclusion:
(1) The task force has no members who diagnose or treat prostate cancer patients, meaning that they have absolutely no clinical experience with prostate cancer or prostate cancer patients, (2) They appeared to have ignored the solicited input by academia, physicians and medical societies who have clinical experience and expertise in prostate cancer, (3) They ignored published studies that demonstrated increased survival with screening, (4) The task force failed to recognize that diagnosis is not the same as treatment and that active surveillance and focal therapy are options in the proper setting. (5) The task force failed to recognize that with PSA screening, survival in African American men improved. However, as I see it, the basic underlying theme of the task force is that the very small risks of biopsy and the small side effect risks of cancer treatment far outweigh the risks and side effects of
prostate cancer, including death. The task force somehow failed to understand the side effects of androgen blockade and other treatments for metastatic prostate cancer, the mental anguish of knowing that one has a terminal disease, and the pain of metastatic prostate cancer.

They failed to understand the toll that this takes upon the family as well. In fact, as further proof, are the following excerpts from recent publications:

**Prostate Ca incidence, mortality declining, report says**
Publish date: JAN 14, 2013

Overall cancer death rates have continued to decline in the U.S. among both men and women, among all major racial and ethnic groups, and for all of the most common cancer sites, including prostate cancer, a recent national report shows. The Annual Report to the Nation on the Status of Cancer, 1975–2009, is co-authored by researchers from the American Cancer Society, the Centers for Disease Control and Prevention, the National Cancer Institute, and the North American Association of Central Cancer Registries. It was published online in the Journal of the National Cancer Institute (Jan. 7, 2013) and will also appear in issue 3, volume 105 of that publication. Between 2000 and 2009, death rates among men decreased for 10 of the 17 most common cancers, including prostate and rectal cancer. The decline in overall cancer death rates continues a trend that began in the early 1990s. From 2000 to 2009, cancer death rates decreased by 1.8% per year among men...

**U.S. Cancer Death Rates Have Dropped 20 Percent Since 1991**
American Cancer Society report credits better screening, treatment for the gains
THURSDAY, Jan. 17 (HealthDay News) — The overall death rate for cancer in the United States has dropped by at least one
fifth over the past two decades, according to new statistics from the American Cancer Society. This steady decline translates to 1.2 million lives spared between 1991 and 2009.

“In 2009, Americans had a 20 percent lower risk of death from cancer than they did in 1991, a milestone that shows we truly are creating more birthdays,” John Seffrin, chief executive officer of the American Cancer Society, said in a news release. Death rates continue to fall for colon, breast and prostate cancers thanks to improvements in the early detection and treatment of these forms of cancer, the new report revealed. But the cancer society noted that more progress could be made if the latest advancements in cancer prevention and treatment were extended to underserved populations. **Between 1991 and 2009...Prostate cancer deaths fell by more than 40 percent during this time frame.**

A report containing similar statistics was released Jan. 7, 2013 on behalf of the cancer society, the U.S. Centers for Disease Control and Prevention, the U.S. National Cancer Institute and the North American Association of Central Cancer Registries. That analysis found that the rate of cancer deaths among men dropped by 1.8 percent per year between 2001 and 2009, “Our efforts in cancer prevention and control are working,” Jane Henley, an epidemiologist in the division of cancer prevention and control at the CDC, told HealthDay at the time. For men, prostate, lung and colorectal cancers will account for half of all new diagnoses. For men, lung, prostate, and colorectal cancer will remain the most deadly forms of the disease...

The cancer society report was based on data from the NCI and CDC, as well as mortality data from the National Center for Health Statistics. The research was compiled in two separate reports that were published in CA: A Cancer Journal form Clinicians.
What is the impact of the USPSTF recommendations? The most important negative effect is that patients who have prostate cancer will go undiagnosed until it is likely incurable. Granted, not all prostate cancer is lethal; however, those patients with lethal prostate cancer will be denied any chance for a cure. (I will provide patient examples below) Also, the younger the patient, the greater chance of dying from undiagnosed and untreated prostate cancer, and our patient population is healthier and living longer. Just because a test is not 100% accurate, that prostate biopsy is not 100% free of any risks or complications, and that surgical or ablative therapy does not cure 100% or have 0% side effects are the wrong reasons to die of prostate cancer. Some patients will refuse screening based upon the task force’s recommendation as will some primary care physicians. Some patients will refuse prostate biopsy for fear of the side effects of the biopsy and possible cancer therapy. Finally, the 2010 Patient Protection and Affordable Care Act directly ties Medicare coverage of a specific preventive service to the grade given by the USPSTF. Therefore, a grade D on PSA means that screening for prostate cancer is no longer covered by Medicare services, and the health insurers may follow suit, essentially denying access to care.

The response by the American Urologic Association and others was immediate and loud, making a public statement at a special event during the Annual Meeting. Representatives from the groups were also joined by Mr. Scott Johnson, who represented the Prostate Cancer Roundtable, a coalition of patient groups, and Dr. William Catalona, who co-authored a response that appeared in Annals of Internal Medicine along with the USPSTF recommendations.

The AUA’s Position:
The American Urologic Society, Large Urology Group Practice Association, American Association of Clinical
Urologists, Society for Urologic Oncology, Society of University of Urologists, and the American Medical Association (AMA) all weighed in to protest, not only the USPSTF recommendations, but the process itself, particularly the lack of transparency and expertise on the task force. “The AUA is outraged and believes that the Task Force is doing men a great disservice by disparaging what is now the only widely available test for prostate cancer, a potentially devastating disease. We hold true to our current position as supported by the AUA’s Prostate-Specific Antigen Best Practice Statement that, when interpreted appropriately, the PSA test provides important information in the diagnosis, pre-treatment staging or risk assessment and monitoring of prostate cancer patients. But not all prostate cancers are life-threatening. The decision to proceed to active treatment or use surveillance for a patient’s prostate cancer is one that men should discuss in detail with their urologists.” Furthermore, Dr. John Lynch of the AUA states: “I think we would all agree that the appropriate use of PSA and DRE, combined with informed consent, especially in at-risk populations, does indeed reduce deaths from prostate cancer. It is a disservice to men to deny them the opportunity for potential treatment and cure, when necessary, for a disease that affects one in six over the course of their lifetime.”

In June 2012, with the support of the AUA and AMA, Reps. Marsha Blackburn (R-TN -7) and John Barrow (D-GA-12), along with Reps. Donna Christensen (D-VI) and Lee Terry (RNE-2), introduced the Transparency and Accountability Act of 2012 (H.R. 5998) which calls for significant changes to the U.S. Preventive Services Task Force (USPSTF) and the process by which the group makes formal recommendations regarding preventive care services. The bill strikes language added by the 2010 Patient Protection and Affordable Care Act that directly ties Medicare coverage of a particular preventive service to the grade given by the USPSTF, which is currently comprised primarily of general practitioners without
input from specialists on specific diseases.

Other key changes called for by the legislation include a mandate to ensure a “balanced representation of primary and specialty care providers” and other key stakeholders in the healthcare community to be involved in development and review of recommendations, and to ensure that the USPSTF be made subject to the same controls that apply to all other federal agencies insuring transparency, fairness and balance, and a comment process before its recommendations can go into effect. Current status of H.R. 5998 With the close of the 112th Congress on December 31, 2012, and the advent of the 113th just beginning, the USPSTF Transparency and Accountability Act will need to be reintroduced into this session. Once it is re-introduced, I encourage patients to contact their representatives to support this important health legislation. In conclusion, PSA remains the cornerstone of prostate cancer screening, and its impact upon early diagnosis and increased survival is very significant, and supported by clinical data. The age at which screening is not necessary or beneficial remains a very personal discussion, as there are old-young and young-old individuals, and the overall health, family history of longevity and the patient’s input are the key factors in the decision process.

Therefore, PSA screening is a personal multifactorial decision and should be continued, and the ill-advised recommendations of the USPTF should be ignored. Furthermore, it should be noted that the USPTF also has previously recommended against screening for prostate cancer in patients over 75 years old, ovarian cancer, and screening women for breast cancer only between ages 50 – 74 years old, and to avoid self exams.

Dr Chinn: This Japanese patient was not screened for prostate
cancer, as he was deemed too old, in 2009, when he was 88 years old. At the time of diagnosis, his PSA had risen to 36.9 and he had metastases to the bone and lungs, and abdominal and pelvic lymph nodes, weight loss and severe pain, and he wanted to die. He is being treated on triple androgen blockade and Xgeva. He is feeling much better, has regained weight, but still requires methadone for chronic pain. His current PSA is now undetectable; he is otherwise quite healthy and active at 92 years of age. Daughter: At age 88, our father, Henry Nishizu, was diagnosed with advanced stage 4 prostate cancer after his biopsy showed the cancer in almost every segment of his prostate. The cancer was detected by Dr. Chinn after Henry, while under the regular care of another urologist, had gone through several years of painful urination, three visits to ER for the inability to urinate, constant severe hip and thigh pain, a failed “microwave” treatment, and a year and a half of self-catheterization. Henry’s prior urologist measured his PSA at ‘7’ but assured the family repeatedly that our father did not have cancer. The doctor stated that he “could feel Henry’s prostate with his finger and it was soft. If it was cancerous, the prostate would feel hard.” He also added that “Henry is so old that even if he did have cancer, something else will kill him before any prostate cancer will.” The nurse confirmed the doctor’s declaration, reading from Henry’s file, “He does not have cancer.” Henry’s brother, who was 89 at the time, encouraged him to try the successful treatment his urologist, Dr. Chinn, had given him or see what else he had to offer. So out of desperation to relieve Henry’s pain, we took our father to Arcadia to see what his brother’s urologist might be able to do for him. After Dr. Chinn discovered the prostate cancer, he sent Henry for x-rays of his bones and found the cancer had spread throughout the bones in his pelvis, right thigh and aortic area. It was now too late to have any special HIFU treatment done on his prostate, as the cancer had metastasized beyond what that machine was capable of curing.
We feel that Henry’s prior urologist was negligent for not even considering the possibility that our father had cancer. The doctor was so adamant about his diagnosis of “no cancer” that his incorrect assessment allowed Henry’s cancer to spread throughout his bones. If that urologist had simply ignored our father’s advanced age and not been so stubbornly against looking further into the causes of his unrelenting discomfort and inability to urinate, the prostate cancer could have been caught much earlier, perhaps before it had had a chance to spread to his pelvic area and thigh. Maybe our father could have avoided the years of deep pain in his bones. It had gotten so bad that he had even considered getting a hip replacement to alleviate the excruciating joint pain. That urologist enabled the cancer growth because of age discrimination.

After undergoing a month of daily radiation on his prostate and the installation of a pacemaker at the City of Hope, in addition to intravenous cancer treatment by a prostate oncologist and monthly Lupron and Xgeva injections by Dr. Chinn, Henry has survived for three years beyond the cancer diagnosis and will be turning 92 in June. We consider him to be lucky to have found a doctor who has treated him “age blind” and has not skipped or withheld treatment because of his advanced age. Henry’s mother lived until just short of 99 and five of the seven siblings have survived well into their 90s. We are forever grateful that our father was given a chance to enjoy a pain-free quality of life a bit longer, thanks to methadone and Dr. Chinn. This patient is 70 years old, and was being screened. His PSA started to rise, but referral was based upon the overall PSA number, not the PSA velocity. So far, his metastatic workup has been negative.
Dr. Chinn: This patient was first seen in 2008 with a PSA of 4.6 at the age of 83 and then was followed by another urologist. The patient returned at the age of 88 with a PSA of 10.3 and a very suspicious DRE. His bone scan is negative, but his CT scan demonstrates extensive metastatic disease to the lymph nodes. He has just been started on androgen blockade. “I am pleased that my urologist has seen fit to treat me actively despite my being 88 years old. I am still ambulatory and appreciate his interest and concern.”