

Prostate Cancer Roundtable

www.prostatecancerroundtable.net

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October 27, 2011

Dr. Robert Cosby
c/o USPSTF
540 Gaither Road
Rockville, MD 20850

Re: USPSTF Proposed Recommendation Statement on Screening for Prostate Cancer

Dear Dr. Crosby,

We, the member organizations of the Prostate Cancer Roundtable appreciate the opportunity to submit the following comments to the United States Preventive Services Task Force (Task Force) draft recommendation statement concerning screening for prostate cancer. The Prostate Cancer Roundtable, representing America's prostate cancer community, is a group of independent, patient-centric, not-for-profit organizations that cooperate to foster the development of policies supporting high quality prostate cancer research, the prevention and early detection of clinically significant prostate cancer, the appropriate care and effective treatment of men with prostate cancer, and the appropriate education of all men about this disease.

The undersigned members of the Prostate Cancer Roundtable are, understandably, severely disappointed by the U.S. Preventive Services Task Force's recent draft "D" recommendation regarding use of the PSA test in screening of otherwise healthy men for risk of prostate cancer. We believe that this draft recommendation:

- Fails to accurately convey the message that the Task Force appears to be making – that the choice to be tested for prostate cancer is an individual one that should be made between a man and his doctor based on complete and accurate data,
- Discourages appropriate individual decision-making by doctors and their patients, and
- Ignores facts associated with the situations faced by a significant number of men in well-defined groups who are at the highest risk of clinically significant disease and at additional risk of dying from prostate cancer if it is not treated early.

Specifically, the Task Force has failed to address the benefits of screening for groups of men well known to be at high risk, including

- African-Americans,
- Men with a family history of prostate cancer, and
- Veterans who have been exposed to Agent Orange.

Men who are at higher risk for prostate cancer are also more likely to be diagnosed with more advanced stages of disease that are more aggressive and more difficult and expensive to treat if they are not diagnosed at the earliest possible stage of their disease. By recommending against the use of the PSA for the early assessment and diagnosis of otherwise healthy men with no symptoms of prostate cancer, a significant number of men will be diagnosed too late to stop localized and/or disseminated progression of their disease, thereby significantly increasing their likelihood of metastasis and prostate cancer-specific mortality.

We would also observe that there have been no published, prospective studies that address the risks and benefits of screening in the high-risk populations mentioned above. Even though a significant number of African-Americans were included in the PIVOT trial, data from this trial are not yet published, and it seems unlikely (given the low recruitment levels) that that trial included sufficient numbers of African-American patients to be able to draw any statistically or clinically significant conclusions.

Since the PSA was introduced in the mid-1990s, mortality from prostate cancer has dropped by 40 percent -- from over 39/100,000 in 1992 to 23.5/100,000 in 2007. Today, 90 percent of all prostate cancers are discovered before they spread beyond the prostate and the 5-year survival rate is nearly 100 percent when treated in these cases. By comparison, the 5-year survival rate for men whose cancer is detected after it has spread beyond the prostate is only 29 percent.

As a test specifically for risk of prostate cancer, current research clearly demonstrates that the PSA test is inconclusive at best. That is not in question. The PSA test itself is not a cancer test. It is diagnostic tool that is an important part of the decision-making process for men and their doctors when monitoring their health. Testing is just the first step in a journey that may include active surveillance and other forms of expectant management or timely treatment for appropriately selected patients. Without this important first step, each additional step is more complicated and reduces the chance for a positive outcome. We would note very specifically that we appreciate the very significant risk for over-treatment of this disease -- which is attributable to historical perceptions of the benefits of early intervention and other drivers. We believe a positive change in the over-treatment problem is attributable at least in part to the revised guidance from the National Comprehensive Cancer Network guideline that appropriate first-line therapy for all men of > 65 years of age with low- and very-low risk disease is active surveillance. This guideline was not in place at the time of conduct of any study on which the Task Force's draft recommendation is based.

Healthy men should not be discouraged from getting a PSA test and should be able to use information associated with the outcome of that test to make an educated decision with their doctor in assessing their health care choices. The way in which the Task Force's recommendation is currently framed most certainly appears to discourage that possibility. We understand the method the Task Force used to reach its conclusions, but we would argue that the very nature of the studies completed to date -- and on which the Task Force's draft recommendation are based -- were never structured to stratify men into risk groups or to provide outcomes data that could show whether men in specific risk groups did or did not benefit from screening. To discourage screening for

such men based on such a complete lack of relevant data appears to us to be callous at best.

The proposed draft recommendation will have a significant impact on the doctor-patient relationship by sending the message to both the man and his health care providers that his access to care options for early detection of prostate cancer should be restricted.

The undersigned organizations include the largest and most active prostate cancer-specific, patient-centric organizations in the US today, from the 37 state chapters of the National Alliance of State Prostate Cancer Coalitions (NASPCC) to the 300 local support groups coordinated by Us TOO International. We all feel frustrated, disappointed, and disempowered with and by the draft recommendation issued by the Task Force, which appears to dismisses any value of PSA testing in healthy men. We hear and are highly familiar with the individual stories, the successes, and the problems, which all begin from a simple PSA test. The constant in all the stories is that patients want early detection and the ability to decide with their own doctor how to proceed clinically.

We are the voices of and for patients and their families, and patients want early detection and the ability to be able to make fully informed decisions in consultation with their doctors and their families. They also need better and more consistent education of the primary care community about the appropriate use of PSA testing and how to discuss such testing with male patients as a component of an annual physical examination and health check.

These comments are submitted by the following members of the Prostate Cancer Roundtable (www.prostatecancerroundtable.net):

- Ed Randall's Fans for the Cure (www.edrandallsfansforthecure.org)
- Malecare Prostate Cancer Support (www.malecare.org)
- Men's Health Network (www.menshealthnetwork.org)
- National Alliance of State Prostate Cancer Coalitions (www.naspcc.org)
- Prostate Conditions Education Council (www.prostateconditions.org)
- Prostate Health Education Network (www.prostatehealthed.org)
- The Prostate Net (www.prostatenet.org)
- Us TOO International Prostate Cancer Education and Support Network (www.ustoo.org)
- Women Against Prostate Cancer (www.womenagainstprostatecancer.org)
- ZERO – The Project to End Prostate Cancer (www.zerocancer.org)