Prostate Cancer Roundtable

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November 8, 2011

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

Re: Response to USPSTF questions about the Prostate Cancer Roundtable comments

Dear Dr. Cosby,

Thanks again for offering the Prostate Cancer Roundtable the opportunity to respond to questions about our original comments. I have included comments from various member organizations. These are complimentary with each other and reflect the views of those members who participated in the discussion, and submitted the original comments.

While we may disagree with the Task Force on the PSA recommendation, we are sympathetic with the daunting nature of the task, and appreciative of the effort.

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Comment on the Pivot Trial from member organization 1:

The Pivot trial indicates the importance of baseline PSAs as part of determining low risk vs. high risk prostate cancers. It also indicates how treatment needs to be separated from diagnosis. - the baseline PSA helps predict mortality outcomes, if doctors believe in the quality and design of the PIVOT trial then they would offer watchful waiting to patients with a PSA less than 10 and a Gleason score less than 6. Without first having the PSA baseline the high risk patients who will benefit from treatment will not receive it.

Concerns about the Pivot trial include the primary VA patient inclusion and 70% of the participants having a low risk Gleason score of 6 or less, the study averages 10 year follow up where half (354) THE men had died. For men with low PSA, low stage and low risk disease prostate cancer mortality was less than 6%. For men with higher PSA or risk disease mortality was 10% to 20%. This mortality reduction is significant to patients.

Comment from member organization 2:

Because of the lack of specific scientific evidence presented in the PLCO and ERSCP trials, all men deemed to be at high risk for prostate cancer should be excluded from

any recommendation against the use of the PSA test for early detection screening. High risk men would include African American men, men with a family history, men exposed to Agent Orange, and men identified as high risk through testing available now and in the future. To issue a "Grade D" rating, the USPSTF must find moderate to high certainty that there is no scientific merit to performing screening. Without the necessary randomized controlled trial, or other peer reviewed scientific evidence, for African American and other high risk men this can not be concluded.

Comment from member organization 3:

(1) The Task Force should specifically recommend baseline risk assessment for prostate cancer for all men and especially for certain groups such as African-American men, those with a certain or an indeterminate family history, and those exposed to Agent Orange.

After risk assessment is made, then routine testing through PSA (and additional adjunctive tests approved by the FDA) would only be recommended for certain men deemed to be at higher risk of being diagnosed with potentially lethal prostate cancer.

(2) Newer prostate cancer-risk tests which will better assess true risk of clinically significant prostate cancer are meant to be used in conjunction with, or following PSA testing already in use. They are not tests in a vacuum. If PSA testing is thrown out (by a "D" Recommendation") these tests will never be used and will deprive men of that crucial additional information which would provide the sensitivity and specificity the Task Force feels is lacking with PSA.

(3) As to the PIVOT Trial, its conclusions make it clear that active surveillance is an appropriate option only for men with truly low-risk disease; it should therefore not be offered or recommended to men outside of that group since it may lead to the development of aggressive disease in patients who needed timely treatment. That is not an answer to the PSA issue.

We need to separate the issue of over-diagnosis from over-treatment. Furthermore, to condemn PSA testing unless a man has prostate cancer symptoms would most definitely lead to more cases of advanced disease at diagnosis, since symptomatology with prostate cancer is almost always a late sign."

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