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Albert L Siu, MD, MSPH
Chair, US Preventive Services Task Force
5600 Fishers Lane, Mail Stop 06E53A
Rockville, MD 20857

RE: USPSTF Draft Research Plan for Prostate Cancer: Screening

Dear Dr. Siu,

Men's Health Network (MHN) is a national non-profit organization whose mission is to reach men, boys, and their families where they live, work, play, and pray with health awareness and disease prevention messages and tools, screening programs, educational materials, advocacy opportunities, and patient navigation.

MHN appreciates the opportunity to provide comments on the USPSTF Draft Research Plan for Prostate Cancer Screening. The recommendation reached by the USPSTF will have significant implications for men at risk of prostate cancer, and the input of patients, healthcare providers and advocates is essential throughout this process, including at this early stage.

We appreciate your consideration of the following comments.

Proposed Key Questions to Be Systematically Reviewed

Key Question 1: We suggest that the focus of this review process be prostate cancer screening overall, with the prostate-specific antigen (PSA) test being a key component of the screening protocol. This would more accurately reflect the current state of prostate cancer screening, where the PSA test is used in combination with other screening tools – such as digital rectal exam (DRE), genomic testing and imaging. PSA is not a prostate cancer test and cannot be used on its own to diagnose a patient, but it is currently an essential tool in helping to determine if cancer is present, and if so, how widespread and/or aggressive it is.

Key Question 2: When reviewing the potential "harms" of the PSA, it is critical to separate harms from a simple blood test from those that may occur due to biopsies or treatments that may or may not take place later in the process. Clearly, not every man with an elevated PSA gets a biopsy or receives treatment such as surgery, radiation, cryotherapy or androgen deprivation therapy. This is particularly true given the rapidly increasing use of additional tools to determine how aggressive the cancer is, and the significant increase in the number of men choosing watchful waiting or active surveillance. The key is the discussion between patient and provider and the decision that the patient makes after weighing all of the information available to him. The PSA test is a simple – but important – tool in making this

informed decision. We suggest that the weight of the inquiry should shift to the decision-making process, with recommendations for improving that process to better serve the patient, and we would urge the Task Force to analyze emerging research on this decision-making process.

Proposed Contextual Question

Contextual Question 3: We believe this is a critical question to ask, as it would broaden the scope of this inquiry to more accurately reflect the current state of prostate cancer screening beyond the PSA test in isolation. We would strongly encourage the USPSTF to make this a "Key Question" that is systematically reviewed for this process.

Proposed Research Approach

Given the nature of prostate cancer research (and the disease itself), we have some concerns with the seemingly limited pool of studies that may be considered under the Proposed Research Approach.

First, we would respectfully request clarification as to why studies prior to 2011 would not be included in the research review. This timeframe may exclude important and relevant publications that pre-date the USPSTF's last review of prostate cancer screening.

Second, while relying on data published in professional journals might make sense for review of some screening guidelines, the world of cancer research, detection, and treatment is moving too fast to rely solely on journal articles that, for the most part, report studies that are 2 – 5 years old, or older.

It would seem prudent for the USPSTF (Task Force) to engage in consultation with researchers and staff at these federal research centers and others:

- National Cancer Institute
- Congressional Directed Medical Research Program
- Veterans Administration
- Centers for Disease Control, including their fine work on the decision making process
- Center for Prostate Disease Research - Uniformed Services University of the Health Sciences

Given the generally slow growth of prostate cancer, weight should be given to long-term studies, looking also to the effectiveness of a baseline PSA in helping to determine likelihood of developing clinically significant prostate cancer at a later age.

Overall Comments

On considering men at higher risk of prostate cancer:

MHN is encouraged to see that the USPSTF will consider variations in screening and treatment by risk factor for those men who are at particularly high risk of prostate cancer due to their age, race/ethnicity, family history and comorbid conditions. We would

encourage the Task Force to consider these nuances both in reviewing the research and in making recommendations that reflect these differences as opposed to a blanket recommendation for all men. We would also encourage you to consider those men who may be at higher risk for prostate cancer due to exposure to environmental toxins such as Agent Orange (including Vietnam Veterans) and debris from the World Trade Center disaster (first responders and others working at the site in the aftermath of the attacks), and those men who do not know their family medical history.

On the harms of <u>not</u> screening

If eventual outcomes and "harms" are to be considered in this research review, then not only should the adverse effects resulting from an ill-advised treatment decision be considered, but the “harms” associated with not screening should also be considered, for not to screen is to condemn too many men to late diagnosis, metastatic prostate cancer and a long and painful path to death.

While the benefits of screening for prostate cancer, including using the PSA – the only test available that can detect possible prostate cancer before it has spread or created an abnormality within the prostate – are reflected in longer studies such as the European Randomized study of Screening for Prostate Cancer (ERSPC), the harms associated with not screening have not been investigated by the Task Force. We suggest that this omission be corrected in the present examination of prostate cancer screening tools.

On the impact of USPSTF Recommendations

The USPSTF now has been given extraordinary influence in the post ACA-passage health delivery structure, with mandated coverage of preventive measures it designates as A or B, and almost certain denial of coverage for those preventive measures it designates as “D” –

‘‘SEC. 2713 42 U.S.C. 300gg–13. COVERAGE OF PREVENTIVE HEALTH SERVICES.
‘‘(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—
‘‘(1) evidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States Preventive Services Task Force;…”

With this enhanced influence comes an immense responsibility, the responsibility to not only examine the repercussions of a preventive measure or screening tool, but also the responsibility to examine the repercussions of not using that measure or tool.

A “D” rating for prostate cancer screening (the current rating) does not mean that men cannot be tested. But it does mean that information about the benefits of testing will be restricted, that the testing will not be covered by insurance, and that, to ask for the test, men will have to overcome all the negative information about prostate cancer screening. So, while these men could request testing, the chances of them knowing to do so, and the chances of their health care provider knowing they may need the test, are low, and life-threatening.

Some examples of the repercussions, post ACA, of the current “D” rating for prostate cancer PSA screening include:

1) HHS/CMS is currently considering a clinical quality measure that would designate prostate screening using the PSA as “unnecessary.” This was posted for comment as: “Non-Recommended Prostate-Specific Antigen (PSA)-Based Screening” (September 2015)

To do so would deny PSA tests to all men, including those in high risk categories and those who do not know their family history.

2) Because of the “D” rating, prostate cancer screening using the PSA is denied to those men who were exposed to the dust and debris of the World Trade Center disaster, even though they have prostate cancer health benefits as a result of that exposure. Given that prostate cancer is generally slow-growing, it is significant that this cancer was added to the benefit package over a decade after the 2001 attack.

In a September 2013 HHS Final Rule, prostate cancer was added to the World Trade Center Health Program as a covered condition:

"In this final rule, the Administrator adds malignant neoplasm of the prostate (prostate cancer) to the List in the WTC Health Program regulations."

But while "*Early detection of cancer in 9/11-exposed populations...is an important adjunct to the WTC Health Program*," the Administrator must deny screening using the PSA for prostate cancer because of the USPSTF "D" rating. (emphasis added)

"Early detection of cancer in 9/11-exposed populations—either as part of medical monitoring of enrolled WTC responders and survivors or part of ongoing research—is an important adjunct to the WTC Health Program. The WTC Health Program adheres to the recommendations of the U.S. Preventive Services Task Force (USPSTF) with regard to coverage for preventive measures, including screening tests, counseling, immunizations, and preventive medications. *The USPSTF recommends against PSA-based screening for prostate cancer. Therefore, PSA-based screening for prostate cancer will not be covered by the WTC Health Program*." (emphasis added)

3) Potential for the denial of prostate cancer screening coverage in Medicare, including the Welcome to Medicare Physical. This coverage was passed by Congress to ensure that older men, who by definition of their age are at higher risk, have access to this critical benefit.

The ACA gives the Secretary of HHS the power to deny payment of any preventive measure given a “D” rating by the Task Force, even if that measure was passed by Congress –

(a) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CERTAIN PREVENTIVE SERVICES.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

‘‘(n) AUTHORITY TO MODIFY OR ELIMINATE COVERAGE OF CER- TAIN PREVENTIVE SERVICES.—Notwithstanding any other provision of this title, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may—
‘‘(1) modify—
‘‘(A) the coverage of any preventive service described in subparagraph (A) of section 1861(ddd)(3) to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and
‘‘(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and
‘‘(2) provide that no payment shall be made under this title for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.’’ (emphasis added)

4) The “D” rating means that high risk men, including those at risk because of race, ethnicity, age, family history, Agent Orange, dust and debris from the World Trade Center disaster, and those men who do not know their medical family history, are not receiving the cautionary health care they should receive so that their physician might provide early treatment if clinically significant prostate cancer is detected.

5) Because of the widely publicized decrease in prostate cancer screenings following the 2012 Task Force “D” rating – there is a significant increase in the number of men presenting with prostate cancer in more advanced stages. (February 2015). www.onclive.com/conference-coverage/gu-2015/Analysis-Shows-Increase-in-Higher-Risk-Prostate-Cancers

“The proportion of patients with prostate cancer and PSA greater than 10 decreased gradually from 2005 to 2011. *However, the proportion of patients diagnosed with intermediate- or high-risk prostate cancer, based on blood PSA level, increased by 3% each year between 2011 and 2013* (P <.0004).” (emphasis added)

Anecdotal evidence, not yet seen in publication, indicates that this phenomenon is repeated in physician offices across the country.

On the importance of consulting experts in prostate cancer diagnosis and treatment

While the USPSTF is composed of national experts in the field of preventive medicine and primary care, we believe it is critical to consult with those medical practitioners who have the most direct experience with patients being screened or treated for the health condition in question. In this case, we would urge you to consult regularly and in a comprehensive manner with urologists and oncologists to incorporate their expertise in your research review as well as your recommendation process.

Thank you again for the opportunity to comment on this important topic for men and their families.

Sincerely,

Men’s Health Network