

***PHEN Comments Submitted to the United States Preventive Services Task Force on the Task Force's Draft Prostate Screening Guideline***

The Prostate Health Education Network, Inc. (PHEN) is a leading patient education and advocacy organization with a focus on African American Men. PHEN's mission is to work towards eliminating the African American prostate cancer disparity. The African American prostate cancer incidence rate is 60% higher and mortality rate 140% higher than white men. These dramatically higher rates represent one of the largest racial disparities for any type of cancer. Evidence supports a faster growth rate and/or earlier transformation to clinically significant prostate cancer in black than in white American Men<sup>1</sup>.



PHEN is pleased with the opportunity to comment on the U. S. Preventive Services Task Force's (USPSTF) draft recommendation on prostate cancer screening from the perspective of its mission. PHEN's position on the USPSTF draft recommendation is that the two randomized controlled trials cited as the primary scientific evidence used do not include a statistically significant number of African American men. The Prostate Lung Colorectal and Ovarian (PLCO) trial conducted in the United States includes approximately 4.5% of African American men. The European (ERSPC) trial does not include any. Clearly the primary evidence used is insufficient to assess the balance of benefits and harms of prostate cancer screening for African American men. Since this evidence is lacking, the balance of benefits and harms cannot be determined. Therefore, according to the USPSTF grade definitions, prostate cancer screening for African American men should remain at the "I" level.

The PLCO trial results show that approximately 8.5% of the men participating in the study were diagnosed with prostate cancer. National Cancer Institute published data shows that overall 1 in 6 men (16.6%) are diagnosed with prostate cancer in the United States. For African American men 1 in 4 is diagnosed (25%) with prostate cancer. The low detection rate within the PLCO trial indicates that the men participating were predominantly men at low risk for the disease. The lack of inclusion of high risk men would invalidate the results for those men. African American men, men with a family history of prostate cancer and men exposed to Agent Orange are deemed to be at high risk for the disease. The evidence used in the United States PLCO trial cannot be properly used to assess the balance of benefits and harms for men at high risk for prostate cancer and for these men as a group, by definition, the USPSTF grade should remain at the "I" level.

PHEN believes that the PLCO trial can only be used as an indicator for the benefits of prostate cancer screening for those men not at high risk for prostate cancer. To "assume" that the results for low risk men can be extrapolated for men at high risk is not scientific evidence.

National Cancer Institute (NCI) models<sup>2</sup> indicate that 45% to 70% of the overall 40% mortality rate decline during the PSA test era could be attributed to early detection using the PSA test. The USPSTF does not have a scientific evidence base that will allow it to ignore this information and completely rely upon data that the USPSTF has categorized as being of "fair" quality, and which excludes men at high risk for prostate cancer.

The USPSTF outlined specific "harms" that PHEN agrees should be addressed and that every effort should be taken to reduce them. However, African American men are suffering a prostate cancer crisis and PHEN's position is that no actions should be taken that will worsen this crisis. To increase the death rate and the associated suffering would worsen the crisis and is the ultimate harm. There is a real and significant risk that a reduction of early detection and treatment, which would be the result of a USPSTF grade "D" rating for high risk men, would increase the African American death rate.

PHEN has studied the "Implementation" scenario outlined within the USPSTF's draft recommendation report which makes assumptions that will probably not hold true for African Americans relative to access to medical care with a "D" grade level as recommended. Private insurance carriers will likely eliminate coverage of the PSA test for screening immediately and PHEN believes this would serve to increase the prostate cancer racial disparity, as only those men with the ability to pay out-of-pocket would get the PSA test. A lack of insurance coverage is one of the major factors cited for the African American mortality disparity.

PHEN appreciates the opportunity to submit these comments and urges the USPSTF to retain the "I" grade level for African American men and those men deemed to be at high risk for prostate cancer. The dialogue created by the USPSTF on the need to reduce the over-treatment of prostate cancer is a meaningful dialogue that PHEN believes should be continued as a primary focus. However, PHEN believes that actions can be taken to reduce over-treatment without risking a reversal of the current decline in the overall prostate cancer mortality rate.

Respectfully submitted,

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President

#### References:

1. "Evidence Supports a Faster Growth Rate and/or Earlier Transformation to Clinically Significant Prostate Cancer in Black Than in White American Men and Influences Racial Progression and Mortality Disparity." Isaac J. Powell,\* Cathryn H. Bock, Julie J. Ruterbusch and Wael Sakr  
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2. Dr. Kathy Cronin on NCI Data and Statistics: PHEN 2011 Summit –  
[www.PHENTV.org](http://www.PHENTV.org)