SB 661 SUPPORT

ZERO
THE END OF PROSTATE CANCER

ZEROCANCER.ORG

Main Phone: 202-463-9455
info@zerocancer.org

The Need for State-Based Prostate Cancer Screening Legislation

In 2012 the United States Preventive Services Task Force (USPSTF or Task Force) updated their screening recommendations for both breast cancer and prostate cancer, recommending against the screening for both cancers. In response, after outrage amongst the breast cancer community, Congress passed Protecting Access to Lifesaving Screenings Act (PALS Act) which circumvented the USPSTF recommendation[1], allowing for the cohort of women the Task Force recommended against mammography screening the ability to receive regular mammograms with no cost-sharing requirements. As more men die of prostate cancer, it is time for the states to fill the gap created by the Task Force allowing men to access common sense screenings to catch prostate cancer while it is still treatable.

Background on the UPSPTF

Established in 1984, the USPSTF was created to make evidence-based recommendations for clinical preventive services to primary care professionals, patients, and families. The sixteen members of the Task Force are appointed volunteers and representing the fields of primary care – specialists (such as urologists and oncologists) do not sit on the panel, which is within the Agency for Healthcare Research and Quality (AHRQ) at the Department of Health and Human Services' (HHS). The Task Force is an independent body, and its work does not require AHRQ or HHS approval.

For years, USPSTF recommendations have been widely referred to in the medical community and used to decide which preventive services physicians and their patients should use. While in some cases insurance companies use these recommendations to decide what to cover under their policies, this coverage was not mandated, and decisions were left largely to providers. The Affordable Care Act (ACA) required private insurance plans to cover USPSTF recommended preventive services without any patient cost sharing (such as copayments, co-insurance, or deductibles), removing a significant obstacle for individuals in need of preventive services. The result of this change has been that those screening tools receiving an A or B rating from USPSTF have benefited from increased access, while other screening tools have experienced a marked decrease in access coupled with confusion over screening best practices[2].

The Problem with the USPSTF PSA Rating

Prostate cancer has very few, if any, symptoms before late stage disease – which only has a 30 percent survival rate. The PSA blood test is an affordable and currently irreplaceable tool to alert providers to the possible presence of prostate cancer before it metastasizes into a fatal diagnosis. In 2012, the USPSTF gave prostate specific antigen (PSA) screening for prostate cancer a "D" rating for all men. That recommendation on contradicted practice guidance issued by the American Urological Association, the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), and the American College of Physicians-American Society of Internal

[1] H.R.2029 - Consolidated Appropriations Act, 2016, https://www.congress.gov/bill/114th-congress/house-bill/2029/text

[2] MacDonald, A. (2011, October 7). New prostate cancer screening recommendation generates controversy and confusion. Retrieved from https://www.health.harvard.edu/blog/new-prostate-cancer-screening-recommendation-generates-controversy-and-confusion-201110073569.

Medicine. The NCCN guidelines, which ZERO endorses, recommend baseline screening beginning as early as age 45[3].

The USPSTF's justification for the "D" rating was due to concerns about false-positives and overtreatment for an often, slow growing cancer. The USPSTF based its 2012 recommendation primarily on two studies of mostly older white men and concluded that the harms of overtreatment outweighed the benefits of early screening (the recommendation emphasized that many men in this category have slow-growing tumors and may die of something else). However, the USPSTF recommendation applied to all age groups and races. The USPSTF did not consider the benefits of screening for younger men (who are more likely to have an aggressive form of the disease), men with a genetic marker or family history of disease, or African-American men, who have almost double the incidence and death rates as their white counterparts.

The lack of nuance in this approach disturbed many in the medical community and has created significant mixed messages about the benefits of screening for prostate cancer. After this recommendation, prostate cancer screening decreased, as did diagnoses of localized prostate cancers, whereas diagnoses of metastatic prostate cancer remained stable[4]. Many experts agree that more men will die because their cancer will not be detected in time to be treated successfully. In fact, **after decades of declining death rates, 2,000 more men are expected to die of prostate cancer in 2019 than in 2018.**

In 2018, the USPSTF issued a new recommendation, upgrading the PSA test a "C" rating for men ages 55-69 and a "D" rating for men 70 and over[5]. The "C" rating suggests that providers should offer the test for high-risk men in that category, but it does not require insurance coverage of the test. The "D" rating for men 70 and above means the PSA test is <u>not</u> recommended for older men – no matter their life expectancy or state of health.

While the USPSTF says that generating data to understand the specific risks and benefits of screening for African Americans and men with a family history is a national priority[6], there are several barriers to the completion of such studies in the near future. Since prostate cancer is slow growing, a comprehensive research study could take twenty years to generate data necessary to make a recommendation. In addition, it is extremely difficult to enroll a sufficient number of African Americans or men with a family history in research trials, and many are concerned such a cohort would not be large enough to support conclusive findings.

<u>The Solution</u>

In the 2018 recommendation report, the USPSTF stated, "given the large disparities in prostate cancer mortality in African American men" filling the PSA screening data gap for this population as well as for men with a family history of the disease, including whether to screen them at a younger age "should be a national priority". Further, the Task Force included this national prioritization language in their "Eighth Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services".

---

[3] National Comprehensive Cancer Network Early Detection for Prostate Cancer Guidelines, https://www.nccn.org/patients/guidelines/prostate/17/

[4] MacDonald, A. (2011, October 7). New prostate cancer screening recommendation generates controversy and confusion. Retrieved from https://www.health.harvard.edu/blog/new-prostate-cancer-screening-recommendation-generates-controversy-and-confusion-201110073569.

[5] USPSTF Screening: Prostate Cancer Recommendation, 2018

[6] Eighth Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services

Considering the many barriers a comprehensive study sufficient for the Task Force would require, including ethical concerns, the time period required of the study, as well as the well-documented challenges in African-American enrollment, we recognize there is no appropriate path forward to fill this glaring research gap.

To that end, ZERO – The End of Prostate Cancer is proposing legislation that would allow, similarly to mammography, men to receive prostate cancer screenings without any burdensome cost-sharing requirements. Further, this legislation would allow men in these highest risk groups to receive prostate cancer screenings at a younger age, catching the disease while it is still treatable and helping fill the USPSTF's "national priority" research gap.