

Patrick Conway, MD
Deputy Administrator for Innovation &
Quality
Centers for Medicare & Medicaid Services
Chief Medical Officer
7500 Security Boulevard
Baltimore, MD 21244

Kate Goodrich, MD
Director
Quality Measurement and Value-Based
Incentives Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Subject: Non-Recommended PSA-Based Screening

November 20, 2015

Dear Drs. Conway and Goodrich,

ZERO - The End of Prostate Cancer (ZERO) appreciates the opportunity to comment on the draft clinical quality measure for the “Non-Recommended screening for prostate cancer using prostate-specific antigen (PSA).” ZERO is a national nonprofit with the mission of ending prostate cancer. We lead the fight to end the disease by advancing research, encouraging action, and providing education and support to men and their families. As you may know, prostate cancer is a disease that will impact one in seven American men in his lifetime. There are nearly 2.8 million men living in the United States with prostate cancer and the American Cancer Society estimates that in 2015 roughly 220,800 men will be diagnosed and 27,540 men will lose their lives to the disease.

ZERO is very concerned the draft measure does not include basic exclusions recommended by a range of provider and advocacy groups or appropriately target the harmful overtreatment of men (instead focusing on over-screening). In addition, we are troubled that the release of the draft measure does not take into consideration the upcoming revision of the U.S. Preventive Services Task Force (USPSTF) recommendation.

CMS' call for comments asked for feedback in three specific areas, for those our comments are as follows. First, this draft measure is too broad in its population catchment to be useful in assessing the quality of care for Medicare-aged beneficiaries. We recommend a more nuanced approach, making exclusions for age and other risk factors, which will allow CMS to accurately assess whether or not patients are encountering physicians who employ best practices in screening across the range of age groups in the Medicare population and accurately adjust for an individual patient's demographic factors and medical history. Second, the measure does not capture data related to physician performance in diagnosis and treatment options and thus cannot be appropriate to assess performance. The absence of ordering a diagnostic blood test does not indicate quality provider performance; quite the contrary. Instead it offers a perverse incentive for physicians to maintain ignorance of the condition, including associated new diagnoses or treatment options, and limit discussion on the topic with patients. Finally, the feasibility of the use of EHRs for data collection is best commented on by providers and EHR designers. However, the promise of EHRs allows for a more accurate provider response, and thus a more detailed screening and treatment recommendation, reflecting best practices that

take into consideration risk factors, individual life expectancy, and disease progression estimations.

ZERO's broad concern with the proposed "Non-Recommended PSA-Based Screening" measure is that it further discourages the use of medically necessary PSA screening in all men over age 18, regardless of age or risk factors, setting up a scenario whereby physicians could be financially penalized for diagnosing a fatal cancer in men who, with treatment, would not die of the disease. The measure is based on the flawed PSA screening recommendations of the USPSTF and contradicts practice guidance issued by the American Urological Association, the National Comprehensive Cancer Network, the American Society of Clinical Oncology, the American College of Physicians-American Society of Internal Medicine, and the American Cancer Society.

The measure, as currently drafted, paints the shortcomings of PSA screening with too broad a brush and fails to make any consideration of individual patient risk factors, including age, race, family history and comorbidities. High risk patients, including men with African-Americans ancestry, veterans, and those with a family history should be considered distinct from the broader population, as reflected by the guidance of many medical societies and patient care groups. Furthermore, the stratification by age is an important component in all the societies' guidance:

- The American Urological Association recommends discussion about risks and benefits of PSA screening in men between the age of 55 and 69 years, and in men 40 to 54 years who are African-American or have family history of prostate cancer.
- The American College of Physicians recommends discussion about risks and benefits of PSA screening in men between the age of 50 and 69 years.
- The American Society of Clinical Oncology recommends discussion about risks and benefits of PSA screening in men with a life expectancy > 10 years.
- The American Cancer Society recommends discussion about risks and benefits of PSA screening in men: over the age of 50 years who are at average risk of prostate cancer and are expected to live at least 10 more years, over the age of 45 years for African-Americans and men who have one first-degree relative diagnosed with prostate cancer at an age younger than 65 years, and over the age of 40 years for men with more than one first-degree relative diagnosed with prostate cancer at an age younger than 65 years.
- The National Comprehensive Cancer Network recommends discussion about risks and benefits of PSA screening in men over the age of 45 years.

That the USPSTF recommendation contradicts practice guidance issued by these expert groups reflects the flaws in the Task Force methodology more than any compelling science arguing against such basic exclusions for race and other risk factors. In fact, the HEDIS measure, which the USPSTF and this draft guidance reference, only focuses on PSA-based screening in men 70 years and older.

In October, the USPSTF initiated the process of updating its PSA recommendation. The public comment period on the draft research plan ends November 26, 2015. Making changes to the current recommendation about Medicare practices until this re-assessment has been completed would appear to be premature at best. ZERO strongly encourages CMS to delay further development of this measure until the USPSTF has completed its update process, including a thorough review of the latest literature and evidence.

Finally, we believe the most important point in the discussion around appropriate use of the PSA test is that the potential harms associated with the use of the test itself are negligible, simply reflecting the potential harms associated a common blood draw. It is the potential harms associated with the improper treatment of prostate cancer that the Task Force seeks to mitigate. A more appropriate policy should discourage *the overly aggressive use of invasive treatment* for localized forms of low risk prostate cancer among men who are unlikely to have clinically significant prostate cancer that could lead to their deaths. Discouraging use of the PSA test in the early detection of prostate cancer will lead to an increase in the number of men diagnosed at an advanced stage of prostate cancer when the disease can no longer be cured with localized treatments.

While the draft guidance recognizes the value of PSA testing in men with a known elevation in the PSA level, or with a diagnosed disorder that affects PSA levels, it would effectively eliminate use of the PSA test in men with no clinical signs or symptoms of a prostatic disorder (prostate cancer specifically included). These exact groups of men, and particularly those who are otherwise healthy between the ages of 45 and 69, serve to benefit the most from a PSA test, which helps to diagnose men at risk for clinically significant prostate cancer before there are any signs and symptoms of the disease. This practice is clearly associated with (if not entirely responsible for) the decline in both the prostate cancer-specific mortality rate and in the risk of a metastatic prostate cancer diagnosis over the past 25 years.

A national clinical quality measure should not be deeply divisive and controversial, as this PSA screening measure would be. Therefore, ZERO joins many other provider groups and patient advocacy organizations in urging CMS to abandon, or delay, this misguided effort.

On behalf of the millions of men and their families fighting prostate cancer, we thank you for the opportunity to share these comments and look forward to working with CMS to ensure that men at risk for prostate cancer are diagnosed early and when diagnosed, receive appropriate treatment.

Best Regards,

Jamie Bearse
President and CEO
ZERO - The End of Prostate Cancer