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FORCE Response to the USPSTF Draft Recommendation Statement for Prostate Cancer: Screening

https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prostate-cancer-screening1

Facing Our Risk of Cancer Empowered (FORCE) is a national nonprofit organization that advocates for individuals and families affected by hereditary breast, ovarian, and related cancers, and families with a BRCA or other inherited genetic mutation that increases risk for these cancers.

The United States Preventive Services Task Force (USPSTF) recently issued a draft of recommended changes to guidelines for prostate cancer screening in men. The 2012 guidelines recommend against PSA screening for men of any age. The new recommendation, which is currently open for public comment, encourages men to talk to their health care providers about when, or if, they need to be screened for prostate cancer. FORCE is concerned that these policy changes in prostate cancer screening guidelines might affect health care coverage for screening of men with BRCA or other inherited genetic mutations, which predispose them to prostate cancer.

The USPSTF panel provides evidence-based guidelines for primary care clinicians and health systems on topics of preventive health. Additionally, the USPSTF guidelines are cited in the Patient Protection and Affordable Care Act (PPACA); therefore, these guidelines impact patient access to care and insurance coverage for men at increased risk of cancer. The "C" recommendation means that "The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences."

According to the USPSTF, the primary goal of prostate cancer screening is to reduce deaths due to prostate cancer. The latest draft recommendation is an improvement over the 2012 decision to recommend against the use of prostate-specific antigen (PSA) testing for the early detection of prostate cancer. While FORCE acknowledges that high-risk communities benefit from increased communication with their health care providers, the recommended grade "C" may have serious negative health implications and make it more difficult for high-risk men to obtain insurance reimbursement for PSA screening.

The following are FORCE's recommendations to the USPSTF for the updated recommendation statement for prostate cancer screening:

Draft: Clinical Considerations

Screening for Prostate Cancer in Men with a Family History

- FORCE recommends a review of the data and extending the evaluation and letter grade of "B" to high-risk men.
    - Although these guidelines were not written specifically for men with BRCA or other cancer predisposing mutations, FORCE is concerned that the proposed recommendation, as written, may have serious negative health implications and make it more difficult for high-risk men to obtain insurance reimbursement for PSA screening due to the "C" recommendation.
    - "PHS Act section 2713 and the interim final regulations require non-grandfathered group health plans and health insurance coverage offered in the individual or group market to provide benefits for and prohibit the imposition of cost-sharing requirements with respect to, the following: Evidenced-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 (USPSTF) with respect to the individual involved.(1)." Thus, for men at high-risk for prostate cancer, coverage of PSA screening with no patient cost-sharing would not be required under the new recommendation.

- Recent research has demonstrated that up to 1 in 9 men with metastatic prostate cancer have an inherited mutation in a prostate cancer predisposing gene which can readily be identified by current genetic testing protocols (2).

- BRCA mutation status is now recognized as an independent prognostic prostate cancer risk factor and marker of a more aggressive tumor and a poorer overall survival.

Research Needs and Gaps

- As researchers learn more about prostate cancer and the important role that genetic testing can play for patients and their families, the focus now needs to be on determining the best way to put this testing into practice.

- Genetic testing for men at high-risk for prostate cancer has preventive health implications for the patient themselves, in terms of their risk of prostate and other cancers, and for their families.

- Preliminary results from the IMPACT Trial (Identification of Men with a genetic predisposition to Prostate Cancer: Targeted screening in BRCA1/2 mutation carriers and controls) support the use of targeted PSA screening based on BRCA genotype and show that this screening yields a high proportion of aggressive disease. To date, the positive predictive value for biopsy using a PSA threshold of 3.0 ng/ml in BRCA2 mutation carriers was 48%—double the PPV reported in population screening studies. For BRCA1 mutation carriers the PPV was 37.5% (3).

- The benefit/risk ratio for prostate cancer screening is likely different for men with BRCA or other prostate cancer predisposing mutations compared to men in the general population. Before grade "C" is given for PSA screening for prostate cancer, it is important to take into account and delineate men for whom these guideline changes might be insufficient.

FORCE appreciates and respects the USPSTF's expertise and the value of reviewing scientific research on critical issues affecting public health, however any evaluation of risk/benefit in determining guidelines needs to take into account and clearly delineate those populations for whom the guidelines may not apply. We urge the USPSTF to amend its recommendation of the grade "C" for the prostate cancer screening guidelines and consider assigning a grade "B" for men at high-risk of developing prostate cancer due to an inherited genetic mutation or other risk factor that predisposes them this disease.

References

1. See https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12.html#fn5

2. Pritchard C, Mateo J, Walsh M, De Sarkar N, Abida W, Beltran H, Garofalo A, Gulati R, Carreira S, Eeles R, Elemento O, Rubin MA, Robinson D, Lonigro R, Hussain M, Chinnaiyan A, Vinson J, Filipenko J, Garraway L, Taplin ME, AlDubayan S, Han G, Beightol M, Morrissey C, Nghiem B, Cheng H, Montgomery B, Walsh T1, Casadei S, Berger M, Zhang L, Zehir A, Vijai J, Scher H, Sawyers C, Schultz N, Kantoff P, Solit D, Robson M, Van Allen E, Offit K, de Bono J, Nelson P. ***Inherited DNA-Repair Gene Mutations in Men with Metastatic Prostate Cancer***. 2016. N Engl J Med. 375(5):443-53.

3. Bancroft E, Page E, Castro E, Lilja H, Vickers A, Sjoberg D, Assel M, Foster C, Mitchell G, Drew K, Mæhle L, Axcrona K, Evans D, Bulman B, Eccles D, McBride D, van Asperen C, Vasen H, Kiemeney L, Ringelberg J, Cybulski C, Wokolorczyk D, Selkirk C, Hulick P, Bojesen A, Skytte A, Lam J, Taylor L, Oldenburg R, Cremers R, Verhaegh G, van Zelst-Stams W, Oosterwijk J, Blanco I, Salinas M, Cook J, Rosario D, Buys S, Conner T, Ausems M, Ong K, Hoffman J, Domchek S, Powers J, Teixeira M, Maia S, Foulkes W, Taherian N, Ruijs M, Helderman-van den Enden AT, Izatt L, Davidson R, Adank MA, Walker L, Schmutzler R, Tucker K, Kirk J, Hodgson S, Harris M, Douglas F, Lindeman GJ, Zgajnar J, Tischkowitz M, Clowes V, Susman R, Ramón y Cajal T, Patcher N, Gadea N, Spigelman A van Os T, Liljegren A, Side L, Brewer C, Brady A, Donaldson A, Stefansdottir V, Friedman E, Chen-Shtoyerman R, Amor D, Copakova L, Barwell J, Giri V, Murthy V, Nicolai N, Teo S, Greenhalgh L, Strom S, Henderson A, McGrath J, Gallagher D, Aaronson N, Ardern-Jones A, Bangma C, Dearnaley D, Costello P, Eyfjord J, Rothwell J, Falconer A, Gronberg H, Hamdy F, Johannsson O, Khoo V, Kote-Jarai Z, Lubinski J, Axcrona U, Melia J, McKinley J, Mitra A, Moynihan C, Rennert G, Suri M, Wilson P, Killick E; IMPACT Collaborators, Moss S, Eeles R. ***Targeted prostate cancer screening in BRCA1 and BRCA2 mutation carriers: results from the initial screening round of the IMPACT study***. 2014. Eur Urol. 66(3): 489–499.