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May 8, 2017

David C. Grossman, MD, MPH
Chairperson, U.S. Preventive Services Task Force
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

Dear Dr. Grossman,

On behalf of the more than 15,000 urologists, more than 200 physician assistants in urology, more than 2,000 urologic nurses and associates, and hundreds of thousands of individuals impacted by prostate cancer in the United States, as well as the overwhelming majority of American men who might be at risk of developing prostate cancer, thank you for the opportunity to provide comments and feedback on the U.S. Preventive Services Task Force's (USPSTF) "Draft Recommendation Statement: Prostate Cancer Screening."

The American Urological Association (AUA) and the undersigned organizations in the urologic community commend the USPSTF on the revised Recommendation Grade of C for men age 55-69 years, which recognizes the need for an individualized approach to screening, and draws from the established evidence regarding PSA screening. From a public health perspective, the acknowledgment that men age 55-69 years should make individualized decisions based on their risk factors and discuss the benefits and risks of screening with their health care providers reflects the appropriate importance of shared-decision making in this context. Furthermore, the inclusion of African American men and those with a family history of prostate cancer as groups at higher risk is to be applauded.

We believe that the USPSTF could further strengthen the Draft Recommendation by considering the concepts and statements listed below:

- Although from a public health perspective the use of a cut-off of age 70 years for a Grade D Recommendation corresponds with an evidence-based assessment of average risk/benefit, this broad-based approach impedes an individual patient from making an appropriate decision based not only on his age, but also factoring life expectancy and personal preferences. Given the results of the ProtecT trial (Hamdy et al., 2016[1]) demonstrating improved outcomes in men with low to intermediate grade prostate cancer

[1] Hamdy FC, Donovan JL, Lane JA, Mason M, Metcalfe C, Holding P, Davis M, Peters TJ, Turner EL, Martin RM, Oxley J, Robinson M, Staffurth J, Walsh E, Bollina P, Catto J, Doble A, Doherty A, Gillatt D, Kockelbergh R, Kynaston H, Paul A, Powell P, Prescott S, Rosario DJ, Rowe E, Neal DE; ProtecT Study Group.. 10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer. N Engl J Med. 2016 Oct 13;375(15):1415-1424.

treated with radiation or surgery compared to active surveillance at 10 years and beyond, there is no reason to believe that potential benefits of shared-decision making conferred to men age 55-69 years could not also be experienced by those age 70 and above provided they have a potential life expectancy of 15 years or more. The possibility that tumors in older men may be more aggressive further supports a more nuanced approach to decision-making in this population.

- The estimation of life expectancy (and thus of potential need for screening) would benefit from consideration of overall health status, including comorbidities, and should not be limited to age. In some cases, men age 70 years and above without comorbidities may have longer life expectancies (15+ years) than younger men with significant comorbidities (Cho et al., 2013[2]).

- There is evidence that after the termination of PSA testing, the incidence of potentially lethal cancers rises to that in the level of nonscreened men (Bergdahl et al., 2013[3]). This again supports the concept that a flexible age at which to discontinue PSA-based screening for prostate cancer, based on individual risk stratification that would include life expectancy, might be preferable to discontinuation at age 70 years.

- The statement that "Adequate evidence from randomized clinical trials is consistent with no mortality benefit of PSA-based screening for prostate cancer in men age 70 years and older" suggests that trials have been conducted in this population and have shown evidence of no benefit. This should be restated to acknowledge that randomized evidence is lacking for this group; therefore, benefits of screening have not been determined.

- The discussion of results of the SPCG-4 trial should include a presentation of age-stratified results. If these form the basis for the Recommendation regarding men age 70 years and above, it should be noted that SPCG-4 data were focused on chronological age rather than life expectancy, thus supporting the approach to screening in the older population suggested above. According to the trial investigators (Holmberg et. al, 2012[4]), the SPCG-4 data suggest that "It is not correct to assume a lack of benefit in men over 65 without considering tumor characteristics, PSA level, and general health status."

[2] Cho H, Klabunde CN, Yabroff KR, Wang Z, Meekins A, Lansdorp-Vogelaar I, Mariotto AB. Comorbidity-adjusted life expectancy: a new tool to inform recommendations for optimal screening strategies. Ann Intern Med. 2013 Nov 19;159(10):667-76.

[3] Grenabo Bergdahl A, Holmberg E, Moss S, Hugosson J. Incidence of prostate cancer after termination of screening in a population-based randomised screening trial. Eur Urol. 2013 Nov;64(5):703-9.

[4] Holmberg L, Bill-Axelson A, Steineck G, Garmo H, Palmgren J, Johansson E, Adami HO, Johansson JE. Results from the Scandinavian Prostate Cancer Group Trial Number 4: a randomized controlled trial of radical prostatectomy versus watchful waiting. J Natl Cancer Inst Monogr. 2012 Dec;2012(45):230-3.

- Recognizing the material presented above, we recommend that the Recommendation for men age 70 years and older be changed from "D" to "I."

- On the lower end of the age scale, we feel that it is reasonable to consider PSA-based screening for prostate cancer in men younger than 55 years. Specifically, for men younger than age 55 years at higher risk (e.g., positive family history or African American race), decisions regarding prostate cancer screening should be individualized.

- The statement that "1 in 5 men who have a radical prostatectomy develop long-term urinary incontinence requiring diaper use" (and a similar statement regarding use of pads) is not reflective of the peer-reviewed evidence base for this Recommendation, which does not comment on diaper use. "1 in 5 experience clinically significant urinary incontinence of some degree" would be a more accurate, evidence-based statement and should be used instead.

- The rates of mortality and complications associated with active treatment of prostate cancer cited in the USPSTF Recommendation are higher than those often noted for modern treatment modalities; these rates should be referenced with up-to-date (within the past 10 years) citations.

- The discussion of Quality of Life results from the ProtecT trial should be updated to include more recent publications (Chen et al., 2017[5]; Barocas et al., 2017[6]), which focus on robotic surgery and modern Intensity-Modulated Radiation Therapy and corroborate the findings from the ProtecT trial. This will serve to underscore the fact that, despite new technologies, the side effects of prostate cancer treatment remain an important consideration and a component of shared-decision making.

[5] Chen RC, Basak R, Meyer AM, Kuo TM, Carpenter WR, Agans RP, Broughman JR, Reeve BB, Nielsen ME, Usinger DS, Spearman KC, Walden S, Kaleel D, Anderson M, Stürmer T, Godley PA. Association Between Choice of Radical Prostatectomy, External Beam Radiotherapy, Brachytherapy, or Active Surveillance and Patient-Reported Quality of Life Among Men With Localized Prostate Cancer. JAMA. 2017 Mar 21;317(11):1141-1150.

[6] Barocas DA, Alvarez J, Resnick MJ, Koyama T, Hoffman KE, Tyson MD, Conwill R, McCollum D, Cooperberg MR, Goodman M, Greenfield S, Hamilton AS, Hashibe M, Kaplan SH, Paddock LE, Stroup AM, Wu XC, Penson DF. Association Between Radiation Therapy, Surgery, or Observation for Localized Prostate Cancer and Patient-Reported Outcomes After 3 Years. JAMA. 2017 Mar 21;317(11):1126-1140.

American Urological Association

Once again, we thank you for the opportunity to comment on this Draft Recommendation and hope that the comments above will be considered in order to further strengthen the Recommendation and best serve the many men at risk for prostate cancer.

Sincerely,

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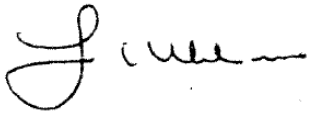

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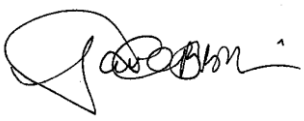

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