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Making the grade: the newest US Preventive Services Task Force prostate cancer screening recommendation

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Precis

The USPSTF recently issued a draft guideline supporting individualized decision making for prostate cancer screening. While we believe this guideline appropriately reflects changing evidence on the benefits and harms of screening, we raise concerns about achieving decision making, interpreting active surveillance data, and initiating screening for African American men.

Keywords

prostate neoplasms; early detection of cancer; prostate-specific antigen; guideline; decision making

Commentary

On April 11, 2017, the US Preventive Services Task Force (USPSTF) issued draft recommendations for prostate-specific antigen (PSA)-based prostate cancer screening.[1] Relying on an updated systematic evidence review, the USPSTF issued a grade “C” recommendation for screening men ages 55 to 69 and a grade “D” recommendation for screening men 70 and older. A “C” recommendation indicates support for individualized decision-making because there is at least moderate certainty that the net benefit is small. The

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media has largely depicted the draft recommendation as a dramatic shift by the USPSTF towards endorsing screening. However, the recommendation is actually more nuanced.

In 2012, the USPSTF issued a “D” recommendation discouraging the use of PSA testing for any asymptomatic man, regardless of age, race, or family history.[2] This recommendation was based on an evidence synthesis of clinical trials which concluded that the net harms of screening outweighed the benefits. Screening was estimated to prevent just 0 to 1 prostate cancer deaths per 1,000 men over a 10-year period. Meanwhile, harms arose from false positive tests, biopsy complications, overdiagnosis, and overtreatment–which often resulted in complications adversely affecting quality of life.

What has changed in the past 5 years? The USPSTF cites new evidence for both greater benefits and reduced harms.[1] Longer-term results from the European Randomized Study of Screening for Prostate Cancer (ERSPC) showed fewer men needing to be screened to prevent one prostate cancer death.[3, 4] Over time this number declined from 1410 to 781—comparable to mammography and colorectal cancer screening. The ERSPC also found that screening 323 men prevented one man from developing metastatic disease.[5] Additionally, the USPSTF downplayed the negative results from the US Prostate, Lung, Colorectal, and Ovarian Cancer Screening (PLCO) trial that strongly influenced the previous evidence synthesis. Given concerns over the high proportion of subjects with prevalent screening before enrollment and the high proportion of PSA testing in the control arm, PLCO investigators now describe the trial as comparing organized vs. opportunistic screening.[6] Pooling results across the two major screening studies is clearly inappropriate.

A major harm of screening is overdiagnosis leading to overtreatment. For over two decades, most men with PSA-detected localized prostate cancers underwent active treatment with surgery or radiotherapy.[7] However, modeling studies estimated substantial overdiagnosis with PSA testing—finding cancers that were not likely to cause clinical problems during a man’s lifetime—implying that many of the men with localized cancers were overtreated.[8] Notably, the Prostate Intervention Versus Observation Trial (PIVOT) trial, conducted among Veterans with localized cancers that were predominantly diagnosed through PSA testing, found no overall prostate-cancer survival benefit for surgery vs. watchful waiting.[9] However, post-hoc analyses revealed that men with intermediate- or high-risk tumor characteristics appeared likely to benefit from treatment, including preventing prostate-cancer deaths and bone metastasis. Therefore, the USPSTF acknowledged new evidence showing that the harms from overtreatment are being mitigated by the increasing uptake of conservative management among men with low-risk cancers.[7] Many of these men are opting for active surveillance-deferring active treatment, undergoing monitoring with at least PSA testing and biopsies, and then being offered active treatment if the cancer appears to be progressing. The American Urological Association and the National Comprehensive Cancer Network have endorsed this management strategy.[10-12]

USPSTF recommendations are very influential. Prostate cancer screening rates and incidence declined in men over age 75 following the 2008 “D” recommendation against screening older men.[13] After the 2011 publication of the draft “D” recommendation, prostate cancer screening and incidence rates dropped for men of all ages.[13] Between 2011 and 2012,

Surveillance, Epidemiology, and End Results (SEER) data showed a staggering 33,519 fewer prostate cancers being diagnosed among men ages 50 and older in the US. An analysis of more recent SEER data found that the incidence rate of distant metastasis increased among men ages 75 and older between 2011 and 2013.[14] Whether this finding will translate into increased prostate cancer mortality is uncertain. However, these incidence trends might reverse if a new "C" recommendation results in more screening.

Screening decisions, though, remain complex. While the systematic evidence review suggests that the balance between benefits and harms now seems to have reached equipoise, the absolute benefit is small and screening can still lead to substantial harm. The USPSTF recommendation clearly highlights the importance of informing men about implications of screening decisions and helping them make a decision based on their values and preferences, an approach consistent with shared decision making, although the USPSTF does not use that term. However, achieving this ideal is challenging and the USPSTF does not provide much guidance on how to accomplish shared decision making. In contrast, the 2012 American Cancer Society guidelines did provide guidance, noting the "complexity of the issues involved and the time constraints faced by health care providers, [and encouraging] providers and patients to use prostate cancer screening decision aids to facilitate the process."[15] Health care providers, though, should not shoulder alone this additional responsibility for shared decision making. Clearly, given the substantial demands on clinicians' time to provide preventive, acute, and chronic care, shared decision making for prostate cancer infrequently occurs, despite the availability of decision aids.[16] Beyond the issue of time constraints, however, there needs to be greater consensus among providers themselves that prostate cancer screening is currently in a state of clinical equipoise. Physician beliefs about the relative benefits and harms of screening strongly influence whether they engage patients in informed and shared decision making.[17] Decision aids for prostate cancer screening have been shown to improve patients' knowledge about the pros and cons of screening, reduce their decisional conflict and distress with their screening decisions, improve their perceptions of personal risk, and encourage more active participation in decision making, but achieving their widespread adoption remains elusive.[18,19] We suggest the need for a concerted public – and professional-awareness campaign that directs men to high-quality culturally appropriate information and tools to facilitate the decision, enabling them to proactively engage with their providers in shared decision making. The message must not be "get screened" or just "talk to your doctor" but rather "you have a decision to make."

One important shortcoming of the draft recommendation is its failure to provide separate guidance for African American (AA) men. The USPSTF acknowledged that, compared to white men, AA men have a significantly higher incidence of prostate cancer, are more likely to develop prostate cancer at younger ages, are more likely to be diagnosed with high-risk disease, and are more likely to die from prostate cancer. As randomized trials have not and will not in the foreseeable future adequately address this issue, we must turn to epidemiologic, observational and modeling evidence for guidance. African American men age 50–54 are more than twice as likely to be diagnosed with prostate cancer than their white counterparts, and, in fact, have a *higher* incidence of prostate cancer than white men age 55–59.[20] Moreover, the modeling report accompanying the draft recommendation cited

recent findings by three Cancer Intervention and Surveillance Modeling Network (CISNET) groups, which "concluded that, if it is agreed that PSA screening is of value for the general population at age 55 years, the models suggest initiating screening 3 to 9 years earlier in AA men."[21] Based on the best available evidence, we think the screening discussion should begin by age 50 for African American men.

Engaging men in shared decision making for the screening decision is necessary but not sufficient for optimizing the benefits of screening. The small proportion of men ultimately diagnosed with a localized prostate cancer should again engage in shared decision making about treatment options, including active surveillance. While the increased uptake of active surveillance is encouraging, men selecting this option will need ongoing support as they recurrently face treatment decisions with each round of surveillance testing. However, the USPSTF seemingly undermines this option by stating that active surveillance is associated with a small increased risk for developing metastatic disease compared with immediate treatment. This is based on results of the United Kingdom "Prostate testing for cancer and Treatment (ProtecT)" trial that randomized men to surgery, radiotherapy, or active "monitoring."[22] At 10-year follow up the risk of prostate cancer mortality was negligible and equal across the treatment arms. The risk for metastatic disease was higher for men in the active monitoring arm compared to those in the active treatment arms, with an absolute incidence increase of 3.3 to 3.9 per 1,000 person-years. However, these results are not necessarily applicable to US men.[23] ProtecT subjects were primarily monitored with PSA alone in contrast to US protocols that recommend routine surveillance biopsies.[10] Furthermore, about 25% of ProtecT subjects had tumors with intermediate-risk characteristics; US protocols are generally restricted to men with low-risk cancers.[10] This point highlights the need to ensure that treatment decisions are informed by the most relevant data.

Six years ago, we (Volk and Wolf) argued against the USPSTF's decision at the time to give prostate cancer screening a "D" rather than "C" recommendation.[24] We now applaud the USPSTF for adjusting its recommendation based on new evidence and acknowledging that screening is a preference-sensitive decision. However, the change from a "D" to "C" should not be seen as endorsing routine screening. The key message is that providers and patients must engage in shared decision making to ensure that men's values and preferences are incorporated into screening and treatment decisions. For this to happen effectively, there will need to be greater public awareness of the issues central to the decision, and greater utilization of high-quality patient decision aids to facilitate these complex decisions.

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