

Screening for Prostate Cancer: U.S. Preventive Services Task Force Recommendation Statement

U.S. Preventive Services Task Force*

Description: Update of the 2002 U.S. Preventive Services Task Force (USPSTF) recommendation statement about screening for prostate cancer.

Methods: The USPSTF evaluated randomized, controlled trials of the benefits of prostate cancer screening; cohort and cross-sectional studies of the psychological harms of false-positive prostate-specific antigen test results; and evidence on the natural history of prostate-specific antigen–detected prostate cancer to address previously identified gaps in the evidence from the 2002 USPSTF recommendation.

Recommendations: Current evidence is insufficient to assess the balance of benefits and harms of screening for prostate cancer in men younger than age 75 years (I statement).

Do not screen for prostate cancer in men age 75 years or older (Grade D recommendation).

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*For a list of Task Force members, see the **Appendix** (available at www.annals.org).

The U.S. Preventive Services Task Force (USPSTF) makes recommendations about preventive care services for patients without recognized signs or symptoms of the target condition.

It bases its recommendations on a systematic review of the evidence of the benefits and harms and an assessment of the net benefit of the service.

The USPSTF recognizes that clinical or policy decisions involve more considerations than this body of evidence alone. Clinicians and policymakers should understand the evidence but individualize decision-making to the specific patient or situation.

SUMMARY OF RECOMMENDATION AND EVIDENCE

The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of prostate cancer screening in men younger than age 75 years. This is an I statement.

The USPSTF recommends against screening for prostate cancer in men age 75 years or older. This is a grade D recommendation.

See the **Figure** for a summary of this recommendation and suggestions for clinical practice.

See **Table 1** for a description of the USPSTF grades and **Table 2** for a description of the USPSTF classification of levels of certainty about net benefit. Both are also available online at www.annals.org.

RATIONALE

Importance

Prostate cancer is the most common nonskin cancer and the second leading cause of cancer death in men in the United States.

Detection

The USPSTF found convincing evidence that prostate-specific antigen (PSA) screening can detect some cases of prostate cancer.

Benefits of Detection and Early Treatment

In men younger than age 75 years, the USPSTF found inadequate evidence to determine whether treatment for prostate cancer detected by screening improves health outcomes compared with treatment after clinical detection.

In men age 75 years or older, the USPSTF found adequate evidence that the incremental benefits of treatment for prostate cancer detected by screening are small to none.

Harms of Detection and Early Treatment

The USPSTF found convincing evidence that treatment for prostate cancer detected by screening causes moderate-to-substantial harms, such as erectile dysfunction, urinary incontinence, bowel dysfunction, and death. These

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harms are especially important because some men with prostate cancer who are treated would never have developed symptoms related to cancer during their lifetime. There is also adequate evidence that the screening process produces at least small harms, including pain and discomfort associated with prostate biopsy and psychological effects of false-positive test results.

USPSTF Assessment

The USPSTF concludes that for men younger than age 75 years, the benefits of screening for prostate cancer are uncertain and the balance of benefits and harms cannot be determined.

For men 75 years or older, there is moderate certainty that the harms of screening for prostate cancer outweigh the benefits.

CLINICAL CONSIDERATIONS

Patient Population under Consideration

This recommendation applies to men in the general U.S. population.

Risk Assessment

Older men, African-American men, and men with a family history of prostate cancer are at increased risk for diagnosis of and death from prostate cancer (1). Unfortunately, the previously described gaps in the evidence regarding potential benefits of screening also apply to these men.

Screening Tests

The PSA test is more sensitive than the digital rectal examination for detecting prostate cancer. The conventional PSA screening cut-point of 4.0 $\mu\text{g/L}$ detects many cases of prostate cancer; however, some early cases will be missed by this cut-point (2, 3). Using a lower cut-point to define an abnormal PSA level detects more cases of cancer.

The proportion of cancer cases detected by lower cut-points that would ever become clinically apparent is unknown; lower cut-points would label many more men as potentially having cancer. For example, lowering the PSA cut-point to 2.5 $\mu\text{g/L}$ would more than double the number of U.S. men between 40 and 69 years of age with abnormal results (4).

Variations of PSA screening, including the use of age-adjusted PSA cut-points, free PSA, PSA density, PSA velocity, PSA slope, and PSA doubling time, have been proposed to improve detection of “clinically important” prostate cancer cases. However, no evidence suggests that any of these testing strategies improves health outcomes (2, 5).

Suggestions for Practice

Given the uncertainties and controversy surrounding prostate cancer screening in men younger than age 75 years, a clinician should not order the PSA test without first discussing with the patient the potential but uncertain benefits and the known harms of prostate cancer screening

and treatment. Men should be informed of the gaps in the evidence and should be assisted in considering their personal preferences before deciding whether to be tested.

Treatment

Because of the uncertainty about the benefits of treating prostate cancer detected by screening men younger than age 75 years, there is no consensus regarding optimal treatment. Current management strategies for localized prostate cancer include watchful waiting (observation with palliative treatment for symptoms only), active surveillance (periodic biochemical monitoring with conversion to curative treatment for signs of disease progression), radical prostatectomy, external-beam radiation therapy, and brachytherapy (or radioactive seed implantation therapy) (6).

If treatment for prostate cancer detected by screening improves health outcomes, the population most likely to benefit from screening will be men age 50 to 74 years. Even if prostate cancer screening is determined to be effective, the length of time required to experience a mortality benefit is greater than 10 years. Because a 75-year-old man has an average life expectancy of about 10 years, very few men age 75 years or older would experience a mortality benefit. Similarly, men younger than age 75 years who have chronic medical problems and a life expectancy of fewer than 10 years are also unlikely to benefit from screening and treatment (2).

Screening Intervals

The yield of screening in terms of cancer cases detected declines rapidly with repeated annual testing. If screening were to reduce deaths, PSA screening as infrequently as every 4 years could yield as much of a benefit as annual screening (7).

Useful Resources

Shared decision-making resources specific to prostate cancer screening for clinicians and patients are available from the Centers of Disease Control and Prevention (www.cdc.gov/cancer/prostate/publications/).

OTHER CONSIDERATIONS

Research Needs and Gaps

Good-quality randomized, controlled trials (RCTs) are needed to establish the effect, if any, of population-based PSA screening on prostate cancer mortality in men younger than age 75 years. The results of 2 ongoing trials, the U.S. Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial and the European Study of Screening for Prostate Cancer, should help to clarify the potential benefits of screening.

Future studies should identify testable characteristics of screening-detected prostate cancer that reliably predict poor health outcomes and that therefore may be indications for treatment. Research is needed to compare the long-term benefits of immediate treatment with delayed

treatment in men with screening-detected prostate cancer. Two ongoing RCTs, the U.S. Prostate Intervention Versus Observation Trial and the U.K. Prostate Testing for Cancer and Treatment Study, are studying these issues.

DISCUSSION

Burden of Disease

An estimated 218 890 U.S. men received a prostate cancer diagnosis in 2007, and 1 of 6 men in the U.S. will receive the diagnosis in his lifetime (8). An estimated 27 350 men died of prostate cancer in the United States in 2006 (1). The median age of death from prostate cancer from 2000 through 2004 was 80 years, and 71% of deaths occurred in men older than 75 years. African-American men have a substantially higher prostate cancer incidence rate than white men (217.5 vs. 134.5 cases per 100 000 men) and more than twice the prostate cancer mortality rate of white men (56.1 vs. 23.4 deaths per 100 000 men) (9).

Prostate cancer is a clinically heterogeneous disease. A substantial proportion of prostate cancer cases detected with current screening methods will never cause symptoms during the patients' lifetime. Modeling studies based on U.S. incidence data suggest overdiagnosis rates ranging from 29% to 44% of all prostate cancer cases detected by PSA screening (10). Because patients with "pseudo-disease" receive no benefit from, and may be harmed by, prostate cancer screening and treatment, prostate cancer detection in this population constitutes an important burden.

Scope of USPSTF Review

The previous review, performed for the USPSTF in 2002, found insufficient evidence that screening for prostate cancer improved health outcomes, including mortality. It also found little evidence on the harms of the screening process or the natural history of prostate cancer cases detected with screening (2). The USPSTF determined that a focused evidence update (5) should systematically review direct evidence that PSA screening reduces morbidity and mortality, evidence on the magnitude and nature of harms associated with false-positive screening results, and evidence on health outcomes of patients with screening-detected prostate cancer who did not receive active treatment.

Accuracy of Screening Tests

The 2002 review noted inherent problems with the use of needle biopsy results as a reference standard to assess the accuracy of prostate cancer screening tests. Biopsy detection rates vary according to the number of biopsies performed during a single procedure: The more biopsies performed, the more cancer cases detected. More cancer cases detected with a "saturation" (≥ 20) biopsy procedure tend to increase the apparent specificity of an elevated PSA level; however, many additional cancer cases detected this way are likely to be clinically unimportant. Thus, the accuracy

of the PSA test for detecting clinically important prostate cancer cases cannot be determined with precision.

Longitudinal follow-up has also been used as a reference standard. A retrospective study found the sensitivity of a PSA level of 4.0 $\mu\text{g/L}$ or higher to be about 91% for detecting aggressive cases of prostate cancer that developed within 2 years of screening; the sensitivity was about 56% for detecting nonaggressive cancer cases within the same period. Among men who did not receive a prostate cancer diagnosis within 10 years, 9% had an initial PSA level of 4.0 $\mu\text{g/L}$ or greater (which translates to a specificity of 91% for any prostate cancer) (11).

Effectiveness of Early Detection and Treatment

A meta-analysis of 2 poor-quality RCTs of population-based screening for prostate cancer using PSA and digital rectal examination found no reduction in prostate cancer mortality in men invited versus men not invited for screening (relative risk, 1.01 [95% CI, 0.80 to 1.29]) (12). A recent RCT reported that men who received PSA screening had a decreased risk for receiving a diagnosis of metastatic prostate cancer (13). The USPSTF assessed the study as providing inconclusive evidence of benefit from screening because of a high likelihood of unequal outcome ascertainment and small absolute numbers of an imperfect intermediate health outcome (metastatic prostate cancer is an imperfect surrogate of prostate cancer mortality because of both high initial response rates to androgen deprivation therapy and competing causes of death). No RCTs have reported health outcomes from the variations of PSA screening that consist of multiple measurements over time (for example, measurements of PSA velocity, PSA slope, or PSA doubling time).

Randomized, controlled trials comparing prostate cancer treatments with watchful waiting have enrolled few patients with screening-detected prostate cancer. An RCT of 695 men with localized prostate cancer reported a small absolute reduction in all-cause mortality in patients assigned to radical prostatectomy; however, only 5.2% of participants had screening-detected prostate cancer, more than 40% presented with symptoms, and 77.8% of the treatment group had stage T2 (palpable) cancer (14). This stage of cancer is more advanced than cancer typically detected by screening. Yet, after a median of 8.2 years, only 14.4% of men in the control group and 8.6% of men in the treatment group had died of prostate cancer.

Screening-detected cancer is biologically less aggressive, is being detected much earlier in its natural history, or both, so it is unlikely that these results could be obtained in a study of screening-detected cancer in this same time frame. Even if the same disease-specific results could be obtained with a longer time frame, competing causes of death would make any reduction in all-cause mortality less than that found in the study. It is noteworthy that in the 372 men who were at least 65 years of age at the time of diagnosis, the 10-year incidence of death from prostate

cancer was similar between the watchful waiting and radical prostatectomy groups, suggesting no benefit from surgery in this age group (14).

Estimate of Magnitude of Net Benefit

In men younger than age 75 years, the USPSTF could not determine the net benefit of screening for prostate cancer because of low certainty about the magnitude of benefits of screening and treatment.

In men age 75 years or older, the USPSTF found no direct evidence of benefits of prostate cancer screening. However, the USPSTF was able to establish an upper bound for the potential magnitude of the benefit of treating screening-detected prostate cancer in this age group, by extrapolating from evidence of treatment for clinically detected prostate cancer in this age group (14). For a population of men with an average life expectancy of 10 years or fewer, the USPSTF determined that the benefits of prostate cancer screening and treatment would range from small to none.

Weighing this magnitude of benefit against the moderate-to-substantial psychological and physical harms associated with prostate cancer screening and treatment, the USPSTF concluded that there is at least moderate certainty that the harms of screening for prostate cancer in men age 75 years or older outweigh the benefits.

How Does Evidence Fit with Biological Understanding?

Prostate-specific antigen screening presupposes that most asymptomatic prostate cancer cases will ultimately become symptomatic cases that lead to poor health outcomes. However, the natural history of PSA-detected, non-palpable, localized prostate cancer is poorly described. No prospective studies have followed a population-based cohort of patients with screening-detected cancer who have had no intervention in order to determine health outcomes resulting from natural progression of the disease. Evidence from small, selected cohorts of men with arbitrarily defined “favorable risk” (that is, with prostate cancer likely to be clinically indolent) suggest a good prognosis for some men with screening-detected cancer; however, the longest of these studies has reported health outcomes from 2 to 10 years after diagnosis only (5).

Update of Previous USPSTF Recommendation

This recommendation replaces the 2002 recommendation. The major change in the current recommendation is that the USPSTF now recommends against screening men age 75 years or older for prostate cancer.

RECOMMENDATIONS OF OTHER GROUPS

Most major U.S. medical organizations recommend that clinicians discuss the potential benefits and known harms of PSA screening with their patients, consider their patients’ preferences, and individualize screening decisions. They generally agree that the most appropriate candidates for screening include men age 50 years or older who have a

life expectancy of at least 10 years. These organizations include the American Academy of Family Physicians (15), American College of Physicians (16), American College of Preventive Medicine (17), and American Medical Association. The American Cancer Society (18) and American Urological Association (19) recommend offering PSA measurement and digital rectal examination to men annually beginning at age 50 years.

From the U.S. Preventive Services Task Force, Agency for Healthcare Research and Quality, Rockville, Maryland.

Disclaimer: Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

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Requests for Single Reprints: Reprints are available from the USPSTF Web site (www.preventiveservices.ahrq.gov).

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Figure. Screening for prostate cancer: clinical summary of a U.S. Preventive Services Task Force (USPSTF) recommendation.

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Screening for Prostate Cancer: Clinical Summary of a U.S. Preventive Services Task Force Recommendation

Population	Men Younger than Age 75 Years	Men Age 75 Years or Older
Recommendation	No recommendation Grade: I (Insufficient Evidence)	Do not screen Grade: D
Risk assessment	Prostate cancer is more common in older men, African Americans, and men with a family history of prostate cancer. The same uncertainties about the effects of screening that apply to other men also apply to these higher-risk men.	
Screening tests	The prostate-specific antigen (PSA) test is more sensitive than the digital rectal examination (DRE). The conventional PSA test cut-point of 4.0 µg/L misses some early cancer. However, lowering the cut-point would increase the rate of false-positive results. Variations of PSA screening have not yet been demonstrated to improve health outcomes.	
Screening intervals	If PSA screening reduces mortality, screening every 4 years may be as beneficial as annual screening.	
Interventions	Management strategies for localized prostate cancer include watchful waiting, active surveillance, surgery, and radiation therapy. There is no consensus regarding optimal treatment.	
Balance of harms and benefits	<ul style="list-style-type: none"> The harms of screening include the discomfort of prostate biopsy and the psychological harm of false-positive test results. Harms of treatment include erectile dysfunction, urinary incontinence, bowel dysfunction, and death. A proportion of those treated, and possibly harmed, would never have developed cancer symptoms during their lifetime. <p>For men younger than age 75 years, evidence is inadequate to determine whether screening improves health outcomes. Therefore, the balance of harms and benefits cannot be determined.</p>	<p>For men age 75 years or older and for those whose life expectancy is 10 years or fewer, the incremental benefit from treatment of prostate cancer detected by screening is small to none.</p> <p>Therefore, harms outweigh benefits.</p>
Suggestions for practice	Clinicians should discuss the potential benefits and known harms of PSA screening with their patients younger than age 75 years. Men in this age group should be informed of the gaps in the evidence, and their personal preferences should guide the decision of whether to order the test.	
Other relevant recommendations from the USPSTF	A list of USPSTF recommendations on cancer screening can be found at www.preventiveservices.ahrq.gov .	

For a summary of the evidence systematically reviewed in making these recommendations, the full recommendation statement (including a summary of research gaps), and supporting documents, please go to www.preventiveservices.ahrq.gov. A grade I recommendation means that the current evidence is insufficient to establish the balance of benefits and harms for screening for prostate cancer in patients younger than 75 years.

Table 1. What the USPSTF Grades Mean and Suggestions for Practice

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer/provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

USPSTF = U.S. Preventive Services Task Force.

Table 2. U.S. Preventive Services Task Force Levels of Certainty Regarding Net Benefit

Level of Certainty*	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: the number, size, or quality of individual studies inconsistency of findings across individual studies limited generalizability of findings to routine primary care practice lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: the limited number or size of studies important flaws in study design or methods inconsistency of findings across individual studies gaps in the chain of evidence findings that are not generalizable to routine primary care practice a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

*The U.S. Preventive Services Task Force (USPSTF) defines *certainty* as “likelihood that the USPSTF assessment of the net benefit of a preventive service is correct.” The net benefit is defined as benefit minus harm of the preventive service as implemented in a general primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

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EXPEDITED REVIEW

Annals invites authors of clinically important randomized, controlled trials to request expedited review and publication of their manuscripts. Send requests to Harold Sox (hsox@mail.acponline.org), Christine Laine (chrisl@mail.acponline.org), Michael Berkwits (mberkwits@acponline.org), or Cynthia Mulrow (cmulrow@acponline.org). We take extra efforts to provide thorough, high-quality, and timely critiques of trials that we expedite. Expedited trials that are accepted are published early online. We also provide readers ancillary material about selected trials, including registered protocols, lists of other ongoing and published relevant trials, lists of relevant published systematic reviews, and links to clinical sources that provide physicians and patients information about the topic of the trial.

Appendix: U.S. Preventive Services Task Force

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†This list includes members of the Task Force at the time this recommendation was finalized. For a list of current Task Force members, go to www.ahrq.gov/clinic/uspstfab.htm.