Screening for Prostate Cancer in U.S. Men
ACPM Position Statement on Preventive Practice

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Introduction: Prostate cancer is the leading cancer in U.S. men, and the third leading cause of cancer deaths. Principal screening tests for detection of asymptomatic prostate cancer include digital rectal examination (DRE) and measurement of the serum tumor marker, prostate-specific antigen (PSA). There are risks and benefits associated with prostate cancer screening. Randomized controlled trials of screening by DRE and PSA are limited to two previously published studies. Two other large-scale randomized controlled trials are currently in progress.

Methods: This study reviewed the efficacy of DRE and PSA for prostate cancer screening found in the medical literature prior to July 2007.

Results: Applications of PSA screening tests used in clinical practice include (1) a PSA cutoff of 4 ng/ml, (2) age-specific PSA, (3) PSA velocity, (4) PSA density, and (5) percent free PSA. Prostate cancer screening can detect early disease and offers the potential to decrease morbidity and mortality. Prostate cancer screening benefits, however, remain unproven, pending results of ongoing trials. There is currently no convincing evidence that early screening, detection, and treatment improves mortality. Limitations of prostate cancer screening include potential adverse health effects associated with false-positive and negative results, and treatment side effects.

Conclusions: The American College of Preventive Medicine concludes that there is insufficient evidence to recommend routine population screening with DRE or PSA. Clinicians caring for men, especially African-American men and those with positive family histories, should provide information about potential benefits and risks of prostate cancer screening, and the limitations of current evidence for screening, in order to maximize informed decision making.

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Introduction

Prostate cancer is currently the leading type of cancer for men in the United States, representing one third of incident cancer cases. It is the second leading cause of cancer deaths in American men (after lung cancer). In 2007, an estimated 218,890 new cases were diagnosed and 27,050 men died of prostate cancer.[1] It has surpassed colorectal cancer deaths, which was ranked second, in 2006. One in every six U.S. men will develop invasive prostate cancer before his death.[1] Age-adjusted incidence of prostate cancer has been increasing over the last 50 years and peaked in the early 1990s, associated mostly with increased early detection due to the introduction of prostate-specific antigen (PSA) in the late 1980s (Figures 1 and 2).[2] There was also a similar trend in prostate cancer–related mortality.[3] Fortunately, the past decade has seen declines in both incident and mortality rates.

From 1973 to 2003, the disease-specific 5-year survival rate for localized or regional prostate cancer was 96%, and was 53% for distant metastases.[4] Genetic, environmental, and social risk factors have been identified for prostate carcinoma, including familial, dietary, hormonal, and possibly environmental carcinogen influences.[5] Prostate cancer incidence increases with age, and men with a family

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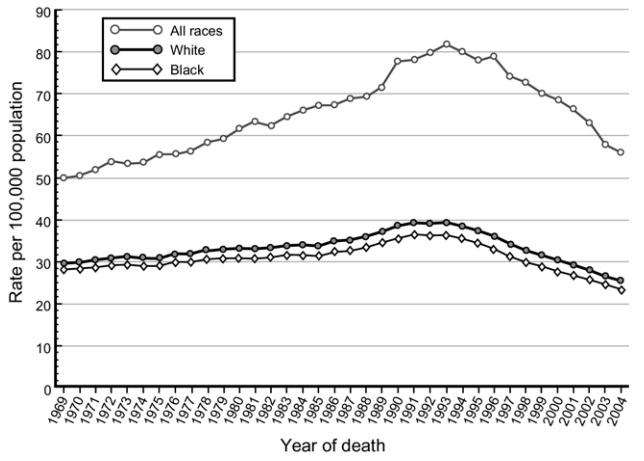

Figure 1. SEER age-adjusted incidence rates by race for prostate cancer, all ages, men. SEER 9 registries for 1975–2004. Age-adjusted to the 2000 U.S. standardized population. SEER, Surveillance Epidemiology and End Results.

history of prostate cancer and African-American men are at higher risk of both developing and dying from prostate cancer. The aim of this statement is to review the efficacy of digital rectal exam (DRE) and PSA for prostate cancer screening found in the medical literature prior to July 2007.

Background

Evidence of Effectiveness of Current Preventive Measures

The principal screening tests for the detection of asymptomatic prostate cancer are the DRE and serum PSA levels. Transrectal ultrasound (TRUS) is no longer considered a first-line screening test for prostate cancer but does play a role in the investigation of patients with abnormal DRE or PSA when guided biopsies are required. With regards to prostate cancer detection, it has been reported previously that DRE has a sensitivity of 55%–68% in asymptomatic men,[6,7] but values as low as 18%–22% have been reported.[8,9] The reported positive predictive value of DRE is 6%–33%.[7,10] Although DRE may not be a sensitive screening test if used alone, it has a positive predictive value of 4%–33% for a PSA value of less than 4 ng/ml.[11] It should be noted that predictive values are highly dependent on the prevalence of the disease in the assessed population and are not independent measures of test performance.

Epidemiologic studies examining the effectiveness of DRE have been mixed. One case–control study showed that cases who died from prostate cancer were less likely than control subjects to have had a DRE in the 10 years before diagnosis (OR=0.51; 95% CI=0.31–0.84),[12] while other case–control studies did not show any significant benefit with regards to morbidity or mortality.[13,14]

To date, there have been only two published randomized controlled trials of screening by DRE and PSA, the Quebec[15] and Norkoping[16] studies. The Quebec trial recruited 46,486 men aged between 45 and 80 years who were randomized 2:1 in favor of being invited for annual prostate cancer screening. The control group received usual care. Screening involved DRE and PSA assay (PSA cutoff of 3.0 ng/ml as the upper limit of normal at baseline). A TRUS biopsy was performed in cases with an abnormal DRE or PSA>3.0 ng/ml. Follow-up screening involved PSA alone. Eleven years after randomization, there was a 62% relative risk reduction in prostate cancer mortality in men who underwent screening. However, there was crossover within the groups as 7% of those in the control group were screened for prostate cancer, and only 23% of the participants allocated to screening underwent screening. When intention-to-treat analysis was performed, no significant differences existed in prostate cancer mortality between the two groups (RR=1.01; 95% CI=0.76–1.33).[17]

The Norkoping trial was conducted in 9026 Swedish men between the ages of 50 and 69 years.[16] This was a quasi-randomized trial in that every sixth participant was invited for prostate cancer screening every 3 years. The control group received usual care. The first two rounds of screening involved DRE alone, whereas the final two rounds of screening involved both DRE and PSA testing. A TRUS biopsy was performed in cases with an abnormal DRE or if the PSA was >4.0 ng/ml. After a 15-year follow-up, prostate cancer diagnosis was more common in the screened group (relative risk=1.47; 95% CI=1.16–1.86). However, there was no difference in prostate cancer mortality between the screened and unscreened groups (relative risk of death=1.04; 95% CI=0.64–1.68).[16] A pooled analysis of the above two studies also showed no difference in mortality between the screened and nonscreened

Figure 2. Age-adjusted total U.S. mortality rates for prostate cancer, all ages, men, for 1969–2004 by race. Age-adjusted to the 2000 U.S. standardized population.

groups (relative risk of death from prostate cancer of 1.01; 95% CI=0.80–1.29).[17]

There are currently two large-scale randomized controlled trials in progress, including the European Randomized study of Screening for Prostate Cancer (ERSPC) and the prostate cancer screening arm of the Prostate, Lung, Colorectal, and Ovarian (PLCO) cancer screening trial. The ERSPC, which started in 1991, includes 183,000 men between 50 and 75 years from eight European countries and should be completed within the next 2 years.[11] Preliminary data from various ERSPC sites have shown that screened men tend to have more favorable clinical and histologic stages of prostate cancer, fewer metastases, and decreased risk of being diagnosed with advanced prostate cancer compared to nonscreened men.[18–20] However, prostate cancer diagnosis was higher among screened men, and mortality data are still pending. The PLCO trial randomized 38,350 of 76,705 U.S. men aged 55–74 years to be screened for prostate cancer via DRE and PSA.[21] The results from this ongoing study will not be available for several more years.

Prostate-specific antigen screening is widespread in the U.S.; in 2000, about 57% of men aged 50 years and older had a PSA test.[22] Current PSA screening modalities include using a PSA cutoff of 4 ng/ml, median/age-specific PSA levels, PSA velocity, PSA density, and percent free PSA. To date, there are no studies showing mortality benefit with any of these modalities. However, for completeness, each of the above modalities is described below.

Baseline PSA (cutoff ≤4 ng/ml). The use of a baseline PSA cutoff of <4 ng/ml for prostate cancer screening is well established in clinical practice. More recently, researchers at Stanford University evaluated 999 first-time biopsy patients aged between 50 and 79 years with 12-core biopsies.[23] When men with normal DREs were studied, the positive predictive values (PPVs) for significant cancer (>3 mm) of a single baseline PSA test between 4.0 and 5.9 ng/ml were 33%, 40%, and 48% for men aged 50–59, 60–69, and 70–79, respectively. For the same groups of patients, the PPVs for high-grade cancer (Gleason score >6) were 14%, 22%, and 26%, respectively. The PPV increased incrementally as baseline PSA values increased to values between 6.0 and 7.9 ng/ml and between 8.0 and 9.9 ng/ml, showing that higher PSA values were associated with higher positive predictive values. However, due to concerns about the potential for false negative results,[24] some would advocate lowering the PSA cutoff to ≤2.5 ng/dl to improve sensitivity for prostate cancer screening.[25] Some centers involved in the ERSPC study used a cutoff PSA of >3 ng/dl as a threshold for prostate biopsy.[11]

Median and age-specific PSA. Published research indicates that the median PSA based on age has a good correlation with both the risk of developing cancer and the risk of having aggressive cancer.[26] However, the increased sensitivity of this method comes at the expense of reduced specificity. Age-specific PSA reference ranges also have been proposed as a means to increase the discriminatory value of detecting clinically relevant prostate cancer in older men and curable prostate cancer in younger men.[27]

Prostate-specific antigen velocity. PSA velocity measures the rate of rise of PSA over time. Observational studies have shown that PSA velocities are not just associated with prostate cancer risk, but also may be a marker of prostate cancer aggressiveness and mortality.[28,29] Although an annual rate of increase of 0.75 ng/ml per year has been proposed as a way to increase the specificity of the PSA test, especially between benign prostatic hypertrophy (BPH) and prostate cancer in PSA levels ≥4 ng/ml,[30] other experts have suggested that the cutoff for PSA velocity should be 0.5 ng/ml/year.[31,32]

Prostate-specific antigen density. The PSA density (PSAD) is the relationship of the PSA level to the volume of the prostate as measured by TRUS. The ratio derived from PSAD was thought to be helpful in discriminating the significance of an elevated PSA in a man with a very large prostate. However, it is now generally not considered to be that useful.[33]

Percent free PSA. Percent free PSA is considered to be more significant than PSAD. It measures the non–protein-bound PSA as a percentage of the total PSA level. It has the potential to improve the ability to distinguish between malignant and benign prostate disease, as the percentage of free PSA is lower in men who have prostate cancer than in men who do not. By improving the specificity of PSA testing for borderline levels (4–10 ng/ml), it can be a useful adjunct for prostate cancer screening.[34] However, there is a lack of consensus regarding the optimal percent free PSA cutoff for screening in clinical practice due to the tradeoffs in sensitivity and specificity.

Shortcomings of PSA Screening

False negatives and false positives. There are several shortcomings with using PSA testing to screen for prostate cancer. Although a PSA level >4.0 ng/ml is generally regarded as the threshold for further diagnostic testing, that level is currently under question following a recent cohort study showing that about 15% of men with initial PSA levels <4.0 ng/ml were diagnosed with prostate cancer at the end of a 7-year period.[24] This false negative rate is similar to that of mammography.[35] False positives in PSA testing are also a concern. The positive predictive value of PSA alone (without DRE) is generally about 30% in epidemiologic studies.[7,36] In the prostate cancer prevention trial,[37] the false-positive rate for a PSA greater than 4 ng/ml was approximately 6%, comparable to that of fecal occult

blood testing for colorectal cancer.[38] False positives have been associated with BPH, prostatitis, other infections (including sexually transmitted diseases), urinary tract procedures, and advanced age. Larger glands are more likely to lead to false-positive PSA tests and BPH can increase the rate of false-positive PSA results.[39] Conversely, a high PSA with a small gland by DRE and or TRUS is more likely to be a true positive.

The Prostate Cancer Prevention Trial showed that men who were randomized to 7 years of finasteride chemoprophylaxis had a 25% decreased risk of prostate cancer versus placebo.[40] However, the treatment group tended to have more high-grade disease. Further analysis showed that this may be due to an increased sensitivity of PSA testing for detecting high-grade disease in the treatment group.[41]

Economic costs. The cost effectiveness of screening for prostate cancer has been difficult to calculate due to the lack of data on screening effectiveness. However, the estimated cost of treating prostate cancer in the U.S. ranged from US$1.72 billion to US$4.75 billion (1990 costs).[42] Implementing a national screening program using PSA and DRE for men aged 50 to 69 years is estimated to cost between $17.6 billion and $25.7 billion in the first year.[8] However, one has to bear in mind that this may not account for the future costs incurred with cases that may have required primary treatment in later years.

Psychological costs. False-positive results of screening tests are not benign; they have a psychological cost. Men who received false-positive prostate-specific antigen test results reported having thought and worried more about prostate cancer despite receiving a negative follow-up (prostate biopsy) result. They also think that the false-positive result makes them more likely to develop prostate cancer. Thus screening may cause undesirable mental health consequences.[43] On the other hand, men who perceive themselves at greater risk of prostate cancer may find some reassurance with a normal prostate cancer screening test.[44]

Screening in High-Risk Population Groups

Men with a first-degree relative (e.g., father or brother) with prostate cancer are at higher risk of prostate cancer compared to the general population, and the risk increases with the number of relatives affected.[45] African-American men are at higher risk of prostate cancer compared to the general population. They have a 1.6- and 2.4-fold greater incidence and mortality rate compared to Caucasian men.[1] Screening rates for prostate cancer among African-American men are lower compared to Caucasian men due to a multitude of factors, including a lack of awareness of screening tests, knowledge about prostate cancer, and perceptions on early detection and consequences of prostate cancer treatment.[46]

Rationale Statement

Prostate cancer is a significant cause of cancer and cancer-related mortality among U.S. men. Screening can detect prostate cancer early, and even though early detection through screening may increase morbidity as a result of treatment, screening has the potential to decrease prostate cancer–associated mortality. However, the benefits of screening are unproven and may not be realized because of the characteristics of this disease (e.g., prevalence of latent clinically insignificant prostate cancer, indolent growth rate, and treatment-associated morbidity). While there is emerging evidence that treatment of early localized prostate cancer versus expectant management can decrease prostate cancer mortality,[47] there is currently no convincing or direct evidence that early detection by screening and treatment improves mortality. Results from a landmark 10-year randomized controlled study comparing radical prostatectomy versus watchful waiting in men with newly diagnosed localized prostate cancer revealed that treatment resulted in reduced risks of prostate cancer–associated death, distant metastasis, and local progression. However, participants were not part of a screening program and the reduction in disease-specific mortality appeared limited to men aged <65 years who were randomized to radical prostatectomy.[47] Given the relatively low death rates associated with early prostate cancer, quality-of-life issues have to be also considered as screening for and treatment of prostate cancer can create short- and long-term discomfort. Widespread screening may burden a large number of men with both psychological and physical complications, which may offset potential benefits. Since the best option depends on personal preferences and quality-of-life expectancy, men considering PSA screening need information about the potential benefits and harms of available options and the quality of the supporting evidence.

Recommendations of Other Groups

The American Urological Association recommends that PSA screening be offered to men beginning at 50 years of age and who have an estimated life expectancy of greater than 10 years.[48] Men with first-degree relatives who have prostate cancer and African-American men may benefit from screening at an earlier age. The American Cancer Society recommends that both DRE and PSA screening be offered annually to men aged 50 years and over and have a life expectancy of greater than 10 years.[49] Both the American Academy of Family Physicians[50] and the Institute for Clinical Systems Improvement[51] concur with the U.S. Preventive Services

Table 1. Benefits and limitations of PSA screening for prostate cancer: key points for patient discussion

Benefits of screening	Limitations of screening
Early detection and treatment of potentially curable stage of prostate cancer (i.e., better chances of survival with localized disease).	Survival benefit from prostate cancer screening has not been demonstrated in rigorous trials.
Reassurance of being at low risk for prostate cancer.	False positive result may lead to increased anxiety and having to experience the discomfort and possible complications associated with biopsy (e.g., pain, hematospermia/hematouria, and infection)
PSA can be obtained with a simple blood test and is widely available.	Prostate cancer may be slow growing and may never advance or progress to cause significant disease or death. Treatment can cause both short- and long-term side effects (e.g., pain, urinary incontinence, and impotence).
	False reassurance from a normal test (false negative), leading to a delayed diagnosis of prostate cancer.

Task Force (USPSTF), which determined that there was insufficient evidence to recommend for or against routine screening using PSA or DRE.[52] The American College of Physicians (ACP) recommends giving men information about the benefits and harms of screening to help them make a decision based on personal preference.[53] The Canadian Task Force on Preventive Health Care recommended against routine screening with PSA (there was insufficient evidence to make a recommendation on DRE).[54]

Recommendation of the American College of Preventive Medicine

The American College of Preventive Medicine (ACPM) concludes that there is currently insufficient evidence to recommend routine population screening with DRE or PSA, concurring with the USPSTF recommendation. The College is in agreement with the ACP that men should be given information about the potential benefits and harms of screening and limits of current evidence in order to make an informed decision about screening. Discussion about screening should occur annually, during the routine periodic examination, or in response to a request by the patient. The effectiveness of prostate cancer screening is questionable in elderly men with competing co-morbidities and men with life expectancies of less than 10 years. Ultimately, a man should be allowed to make his own choice about screening, in consultation with his physician, taking into consideration personal preferences and life expectancy. If the patient prefers to defer to the clinician or is unable to make a decision regarding screening, then testing should not be offered as long as the patient understands the benefits, potential limitations, and adverse effects associated with screening. Key points that should be communicated during the patient encounter regarding prostate cancer screening are listed in Table 1.

Pending resolution of ongoing controversies, screening for prostate cancer among African-American men and those with a family history of prostate cancer has the potential to detect treatable forms of disease that are more likely to occur in these groups than in the general population.[45] While the usual age for prostate cancer screening is between 50 to 70 years in average-risk men, it has been suggested that those who are at high risk may benefit from earlier screening beginning at age 45, while higher-risk men (those with two or more first-degree relatives with prostate cancer before age 65) be screened at age 40.[49] Granted that prostate cancer is more likely to be found in high-risk men, issues pertaining to tumor grade have yet to be resolved (that is, optimal grade of tumor that a screening test should detect to confer a benefit in survival or morbidity), and there is still no evidence establishing effectiveness of screening in high-risk men. In the meantime further studies are needed to establish the efficacy and optimal age at which prostate cancer screening should be initiated in these high-risk population groups.

Additional Resources

The ACPM recognizes the challenges of presenting complex information on prostate cancer screening in the course of a brief office visit. Therefore, in addition to the key points listed in Table 1, additional tools can be utilized to assist the clinician to communicate the benefits and harms of prostate cancer screening with the patient. Resources from easily accessible national and reputable medical websites can supplement the face-to-face counseling in the office to aid the patient in the decision-making process. Medline plus, a service of the U.S. National Library of Medicine (NLM) and the National Institutes of Health (NIH), provides a comprehensive collection of resources on prostate cancer, including links to additional information pertaining to screening.[55] Both the National Cancer Institute (NCI) and Mayo Clinic websites provide an excellent overview of prostate cancer screening.[56,57] The Centers for Disease Control and Prevention (CDC) have decision guides specifically targeted toward African-American

and non-African-American men.[58,59] In addition, a prostate cancer risk calculator can provide quantification of prostate cancer risk to aid decision making in prostate cancer screening.[60]

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Figures 1 and 2 on page 165 were printed in error. The correct figures are printed below. The authors and publisher regret the errors and any inconvenience they caused the reader.

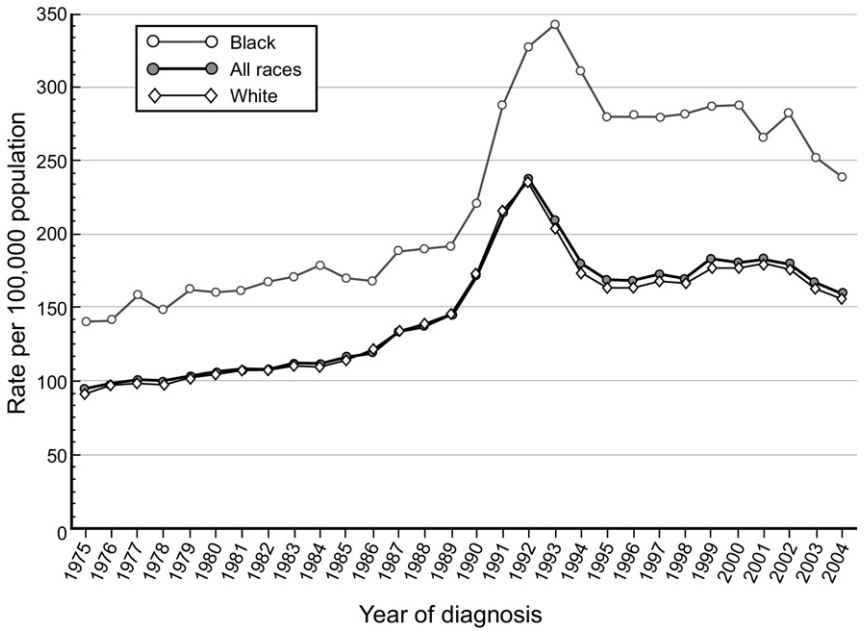

Figure 1. SEER age-adjusted incidence rates by race for prostate cancer, all ages, men. SEER 9 registries for 1975–2004. Age-adjusted to the 2000 U.S. standardized population. SEER, Surveillance Epidemiology and End Results.

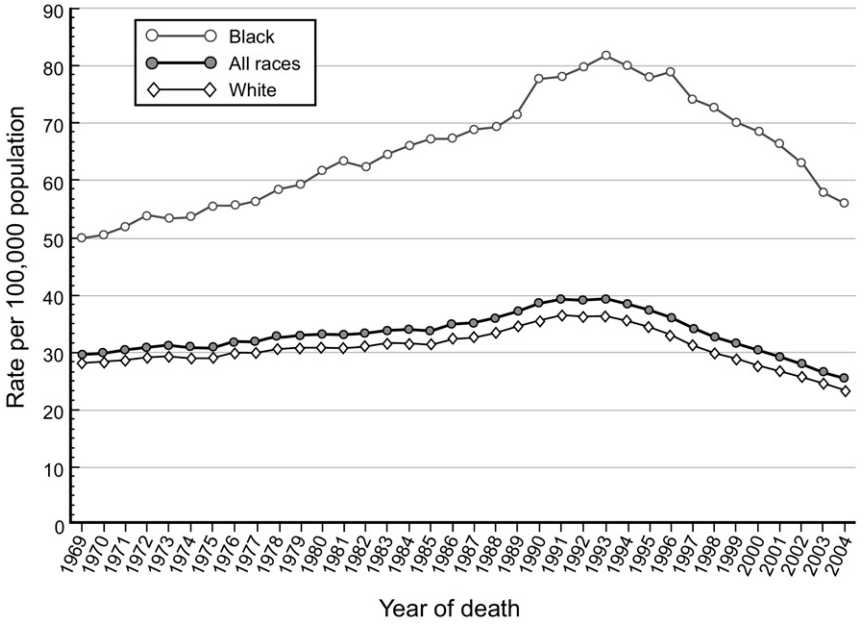

Figure 2. Age-adjusted total U.S. mortality rates for prostate cancer, all ages, men, for 1969–2004 by race. Age-adjusted to the 2000 U.S. standardized population.

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