APPLIED EVIDENCE

New research findings that are changing clinical practice

Kendra Schwartz, MD, MSPH, Bruce Deschere, MD, MBSA, and Jinping Xu, MD

Department of Family Medicine, Wayne State University School of Medicine, Detroit, Mich

Screening for prostate cancer:
Who and how often?

Better use could be made of the PSA assay, and less frequent testing may not jeopardize patients' outcomes

Practice recommendations

■ Engage patients in shared decision making by discussing the benefits and risks of prostate cancer screening. Patients who review educational pamphlets before an office visit engage more fully in the decision-making process. (**B**)

■ If performing prostate cancer screening, limit to men with greater than 10 years life expectancy. (**B**)

■ Because the lead time of a diagnosis based on PSA screening is estimated to be 5 to 7 years, PSA screening every other year is unlikely to cause a loss of sensitivity. (**B**)

■ Men with tumors with a Gleason score less than 5 are the best candidates for "watchful waiting," having a favorable 20-year survival. (**B**)

Prostate cancer screening in asymptomatic men remains controversial, and it is difficult to present its benefits and risks quickly in a way that is understandable to patients. Yet many expert groups agree that physicians should enter into a mutual decision-making process with patients.[1–3]

This article reviews the latest information relevant to the controversy, offers "talking points" for family physicians to use when discussing screening with patients, and lists websites that patients may find helpful when making a decision about prostate cancer screening.

For this review, we searched for recent articles that are generalizable to a primary care population and of the highest evidence level available. We preferentially discuss population-based studies, studies from randomized trials of screening, and meta-analyses, rather than results that are hospital- or clinic-based. For a complete systematic review of this topic (from 2002), readers are referred to one conducted for the Agency for Healthcare Research and Quality.[4] (See **Scope of the problem**).

■ Key components of the controversy

How effective is screening?

A good screening test does 2 things. First, it detects a disease earlier than it would be detected with no screening at all, and it does so with sufficient accuracy to avoid a large number of false-positive and false-negative results.

Second, it leads to treatment of early disease that will likely produce a more favorable health outcome than waiting to treat patients who have signs and symptoms of disease.[9] Unfortunately it is still unclear whether screening tests for prostate cancer meet these 2 criteria.

CORRESPONDING AUTHOR
Kendra Schwartz, MD, MSPH, 101 E. Alexandrine, Detroit, MI 48201, E-mail: kensch@med.wayne.edu

Skewed numbers. Yes, estimates of false-positive and false-negative results are available from numerous studies of different populations. However, in most studies, only men with abnormal test results receive a biopsy. Men with normal screening test results are not biopsied. Therefore the number of false negatives (and true negatives) is unknown. Furthermore, these estimates are often based on patients from urology clinics, a group more likely to have disease, thereby increasing the positive predictive value of a given screening test.

Whether current screening methods—in particular, prostate-specific antigen (PSA)—identify prostate cancers destined to become clinically relevant is also unknown. If screening does identify such cancers, a decrease in prostate cancer mortality among men who were screened is expected. If it does not, overdiagnosis and treatment of clinically insignificant cancers will negatively impact the quality of men's lives without extending their life spans.

Clinical variability of the disease

The natural history of prostate cancer is uncertain. If cancer is left unidentified or untreated, more men will die *with* prostate cancer than *of* prostate cancer.

Clinically, prostate cancer ranges from an asymptomatic slow-growing tumor to an aggressive cancer with painful metastases. Treatment may be unnecessary at one end of the spectrum and palliative at the other.

The goal of screening is to identify slow-growing tumors destined to extend beyond the prostate while they are confined to the prostate and amenable to treatment, thereby decreasing the risk of prostate cancer morbidity and death.

Usually low morbidity. For a 50-year-old man, the risk of being diagnosed with prostate cancer by age 80 years is 15%; however, the same man has a 1.4% chance of dying of prostate cancer over that 30-year period.[7] This 10-fold difference shows that prostate cancer usually is not a fatal illness. Another indication of the often benign nature of the disease is the high per-

Scope of the problem

Adenocarcinoma of the prostate is a significant public health burden. Age, family history, and race are the only known risk factors. Most cancers (86%) are diagnosed while still confined to the prostate; however, invasion beyond the capsule is sometimes not apparent until surgery.

Incidence. In 2005, there will be approximately 232,090 new cases of prostate cancer.[5] American men have a 17% chance of being diagnosed with prostate cancer; African Americans have a 65% greater risk of developing prostate cancer than Caucasians.[6] In fact, African Americans have the highest prostate cancer annual age-adjusted incidence rates in the world: 272/100,000 compared with 164/100,000 for Caucasian Americans.[6] The rate for US Asian/Pacific Islander and Hispanic men is less than that for Caucasian Americans.

Mortality. There will be approximately 30,350 prostate cancer deaths in 2004.[5] There is 3% chance of dying from prostate cancer; however, the risk of death is about 55% higher for African American men than Caucasian American men.[6]

Risk factors other than race. Risk of prostate cancer diagnosis increases with age: 1 in 48 men aged 40 to 59 years will be diagnosed with prostate cancer, while 1 in 8 men aged 60 to 79 years are at risk.[7] A man who has a first-degree relative with prostate cancer is 2.4 times as likely to be diagnosed with prostate cancer as a man with no affected relatives.[8]

centage of prostate cancers identified at surgery for bladder cancer; up to 40% of specimens contain unsuspected prostate cancer (level of evidence [LOE]: **2c**).[10,11]

Most clinical diagnoses (80%) and prostate cancer deaths (90%) occur among men older than 65 years;[6] the median age at diagnosis is 72 years.[12] More than 75% of men older than 85 years will have histological prostate cancer (LOE: **2c**).[13] Many men live with their disease for more than 10 years, but do not die of it (LOE: **2c**).[12] Additionally, a review of several decision analyses indicates that men 75 years of age and older are not likely to benefit from screening and aggressive treatment (LOE: **2a**).[14]

Hence the recommendation: if performing prostate cancer screening, limit to men with greater than 10 years life expectancy.[15]

TABLE 1

Characteristics of screening tests for prostate cancer

TEST/SOURCE	DESCRIPTION (LEVEL OF EVIDENCE)	SN ESTIMATE (%)	SP ESTIMATE (%)	LIKELIHOOD RATIO	PPV (%)
Abnormal DRE[18]	Meta-analysis of studies that performed biopsies for abnormal DRE (**2a**)	59 (51%–67%)	94 (91%–96%)	+ 9.8 – 0.4	28 (20–36)
Abnormal DRE[17]	Meta-analysis of studies that performed biopsies for abnormal DRE or PSA (**2a**)	53.2	83.6	+ 3.24 – 0.56	17.8
PSA >4 ng/mL[12]	Review of multiple cohort studies with diverse populations, not systematic	Mean = 71	Mean = 75	+ 2.8 – 0.30	37
PSA >4 ng/mL[19]	Longitudinal retrospective study of prostate cancers that developed within 2 years of PSA test (**3b**)	73.2	85.4	+ 5.0 – 0.2	
PSA >4 ng/mL[20]	Nested case-control study of prostate cancers that developed within 5 years of PSA test in a cohort study (**3b**)	86	94	+ 14.3 – 0.15	
PSA > 4 ng/mL[17]	Meta-analysis of studies that performed biopsies for abnormal PSA or DRE (**2a**)	72.1	93.2	+ 10.2 – 0.30	25.1

Sn, sensitivity; Sp, specificity; PPV, positive predictive value;
PSA, prostate-specific antigen; DRE, digital rectal examination.

■ Details of screening tests
Digital rectal examination insufficient

Digital rectal examination (DRE)—palpating the prostate gland to determine size and consistency—is one screening tool for prostate cancer, usually performed in conjunction with PSA testing.[15] It is not a difficult or expensive test, but its reproducibility is only fair, even among experienced urologists (LOE: **2b**).[16]

The sensitivity and specificity of DRE can only be estimated because men with a normal finding on DRE are not routinely biopsied in any studies (**TABLE 1**).[17,18] One of two pertinent meta-analyses[18] included studies that followed men with a negative DRE finding for development of prostate cancer (LOE: **2a**). Both meta-analyses of DRE as a screening tool found that the included studies were heterogeneous in their study populations and definition of abnormal DRE test result (LOE: **2a**). The positive predictive value (PPV) of DRE was 28% in one meta-analysis and 18% in the other.

### Prostate-specific antigen: Improving its clinical usefulness

Prostate-specific antigen (PSA), first detected in serum in 1979, is a protein produced by prostate epithelial cells. It was originally used to follow men treated for prostate cancer for evidence of recurrence. In the late 1980s, it became widely used in the US to screen for prostate cancer.

An elevated PSA level is suggestive but not diagnostic of prostate cancer. Elevated levels also occur with advancing age, increased prostate size, and prostatitis, and following ejaculation. Prostate manipulation such as biopsy and surgery (but not digital examination) also elevates PSA.

Customary cutpoint. An abnormal serum PSA level is commonly regarded as 4 ng/mL or greater. At this cutpoint, most studies report sensitivity for cancer of around 70%, with more variability in specificity (**TABLE 1**). Again, in most studies that report sensitivity and specificity,

Calculating the Gleason score
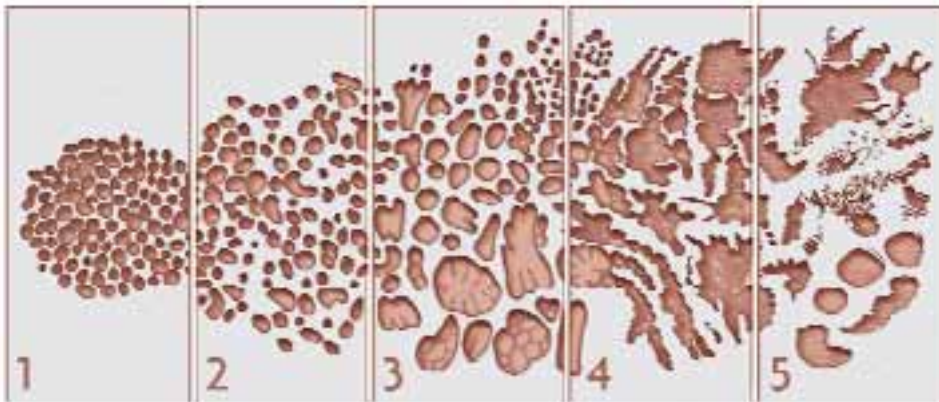
The Gleason score is based on the level of differentiation and growth pattern of prostate cancer cells. Cancer cells that closely resemble the normal prostate cells when viewed under low-power magnification are well differentiated. Cancer cells that do not retain the structure of the surrounding normal cells are poorly differentiated. Scores range from 1 to 5.

In examining histologic samples of a patient's prostate tissue, the pathologist will identify the 2 most commonly occurring patterns (types of differentiation) among the cancer cells and assign a numerical value to each pattern. The 2 numbers are then added to yield the final Gleason score. If a single pattern dominates, the pathologist will simply double the corresponding value.

Total scores range from 2 to 10. Scores in the range of 2–4 are considered well-differentiated, 5–7 are moderately differentiated, and 8–10 are poorly differentiated. In general, the higher the score, the worse the prognosis. Men with well-differentiated tumors that are treated conservatively have minimal risk of dying from prostate cancer.

ILLUSTRATION BY: JENNIFER FAIRMAN

men with a PSA level less than 4 ng/mL did not undergo prostate biopsy; therefore, the number of false negatives and true negatives are only estimates.

In nested case-control studies of longitudinal cohorts, eligible cases were defined by the length of time between an abnormal PSA result and prostate cancer diagnosis, while controls were men who were not diagnosed with prostate cancer during the same time period (however, a biopsy was not usually performed). The PPV of an abnormal PSA level is estimated at 25% to 37%. As a comparison, the PPV of a positive mammogram finding for women 50 to 59 years is 4% to 9%, and 10% to 19% for women age 60 to 69.[21]

Suggested strategies to improve PSA accuracy. Approximately 70% of men with an elevated serum PSA level do not have cancer. To decrease the number of unnecessary biopsies, experts have suggested several strategies:
- using DRE with PSA
- calculating a ratio of free PSA (unbound to protein) or complexed PSA (bound to protein) to total PSA
- measuring PSA density, which incorporates the volume of the prostate gland and is subject to observer variability in prostate volume measurement
- recording PSA velocity, which is the annual rate of change in PSA level and requires 3 or more measurements.

Revise the cutpoint? The cutpoint of 4 ng/mL has been deemed too high by some clinicians. A recent report of men enrolled in a large prostate cancer prevention trial found that among the 9459 men receiving placebo, 2950 had a PSA level of 4 ng/mL or less and had normal prostates on DRE (LOE: **1b**).[22] All 2950 underwent a prostate biopsy; 449 (15.2%) were positive for cancer. Nearly 30% of those had a

TABLE 2

Estimates of risk associated with specific prostate cancer treatments 12 months or more after treatment

TREATMENT OUTCOMES	RADICAL PROSTATECTOMY (%)	EXTERNAL BEAM RADIATION (%)	BRACHY-THERAPY* (%)	ANDROGEN DEPRI-VATION THERAPY (%)	UNTREATED (%)
Death within 2 months of treatment	0.5–0.7	0.2–0.5	0.2–0.5		
Urinary problems:					
Incontinence	10–50	2–16	6–16		
Wearing pads	5–32	2–12	2–16		
Urinary bother†	4–20	3–15	3–16		
Sexual problems:					
Impotence	50–80‡	30–60	20–60**	70–92	20–50
Sexual bother	10–40	10–30	10–18	25–38	10–32
Bowel problems:					
Bowel problems§	9–15	6–35	4–20		
Loose stools/ diarrhea	15–21	6–37	4–10		
Bowel bother	1–3	4–12	2–10		
Other symptoms				Breast swelling: 5–25 Hot flashes: 50–60	

* Fewer studies on brachytherapy are available, especially those with long-term follow-up; therefore, these findings are less certain than other entries.
‡ Includes nerve-sparing prostatectomy.
† EBRT and brachytherapy patients are more likely to experience irritative voiding symptoms
  (i.e. dysuria, urgency and hesitancy and noctoria), while RP patients are more likely to experience incontinence.
** Impotence risk gradually increases with time after treatment.
§ Includes symptoms such as painful bowel movement and urgency
Sources: references 14, 50–53, 65–71.

PSA level of 2 ng/mL or less.

Approximately 25% of tumors in men referred for biopsy because of abnormal PSA or DRE findings are thought to be discovered by chance due to the biopsy procedure and the high prevalence of disease (LOE: **2c**).[23] Furthermore, a recent study indicates that annual PSA fluctuation is substantial; 45% of men who initially had a value of 4 ng/mL or greater, subsequently had a normal level (LOE: **2b**).[24] Isolated abnormal levels should be confirmed before referral for biopsy.

■ Identifying clinically relevant cancers

The continued controversy around PSA screening relates to the potential over-diagnosis of localized prostate cancers that are not likely to become clinically significant. The ideal screening test would predictably identify cancers likely to progress.

Screening over-detects

Several computer simulations have estimated the amount of over-detection of prostate cancer. The National Cancer Institute's *Surveillance, Epidemiology and End Results* (SEER) registry data demonstrated that the proportion of prostate cancer found through PSA testing that otherwise would not have been diagnosed in the patient's lifetime was 29% for white men and 44% for black men (LOE: **2c**).[25]

An Italian study found that the proportional excess of cancers detected by screening over those that would have been

expected in the absence of screening is greater than 50% (LOE: **2c**).[26]

Finally, a model based on results from the European randomized study of prostate cancer screening estimated that a screening program with a 4-year interval from age 55 to 67 has an over-detection rate of 48% (cancers that would not have been diagnosed in the absence of screening) (LOE: **2c**).[27] Additionally, the authors determined that such screening might advance prostate cancer diagnosis by at least 10 years. Previous estimates of diagnosis lead time have been in the 5- to 7-year range (LOE: **2b**).[28] These findings indicate that screening intervals of 2 to 4 years are unlikely to cause a loss of sensitivity.

Spread of tumor

Spread of the tumor beyond the prostate capsule is a poor prognostic sign.[29] Unfortunately, this occurrence is often not known until surgery, and the result usually is an "up-staging" between clinical diagnosis and pathological diagnosis. Nevertheless, most cancers (86%) diagnosed between 1992 and 1999 were localized to the prostate.[6] Because these cancers have not spread beyond the prostate at the time of diagnosis, they are more likely to be curable. They are also more likely to represent tumors that may grow so slowly that the host will die of something other than prostate cancer.

Gleason score

Gleason score is another predictor of cancers destined to become clinically relevant (**FIGURE 1**). A Gleason score of 7 or greater denotes moderate to poor cellular differentiation and indicates a greater potential for progression than lower Gleason values.[29] A recent long-term follow-up report on a cohort of men with localized cancer treated conservatively demonstrated that men with low-grade tumors (Gleason score 2–4) have a minimal risk of dying from prostate cancer after 20 years, while men with high-grade tumors (Gleason score of 8–10) have high probability of prostate cancer death within 10 years of diagnosis (LOE: **2b**).[30] Ecological[31] and

		TABLE 3

Percentage of patients with specific complication of transrectal prostate biopsy

CONDITION	TYROL STUDY[63]	EUROPEAN RANDOMIZED STUDY OF SCREENING[64]
Gross hematuria >1 day	12.5%	22.6%
Hematospermia	29.8%	50.4%
Significant pain	4.0%	7.5%
Rectal bleeding	0.6%	1.3%
Nausea	0.8%	0.3%
Fever >38.5° C	0.8%	3.5%
Epididymitis	0.7%	0.07%
Sepsis	0.3%	Not available
Hospitalization	Not available	0.5%

Tyrol study[63]: LOE: 2b, N=6024 biopsies; ERSS study[64]: LOE: 1b, N=5802 biopsies.

clinical studies[32] indicate that a substantial proportion of PSA-detected cancers are moderately differentiated. This is especially true in a first round of screening; as in the European randomized study of screening, where 36% of cancers were Gleason score 7 or higher (LOE: **1b**).[33]

■ Is declining mortality a sign of screening success?

Prostate cancer mortality has been declining since the mid-1990s in numerous parts of the world; the US,[6,34] Canada,[35] Australia,[36] and the United Kingdom[37] have all reported a reduction in the rate of prostate cancer deaths. Advocates of PSA screening point to this trend as evidence of the effectiveness of screening. But such ecological data are difficult to interpret. For instance, although much less PSA screening is performed in the UK, mortality trends are similar to those in the US where PSA testing has been used more widely.[38]
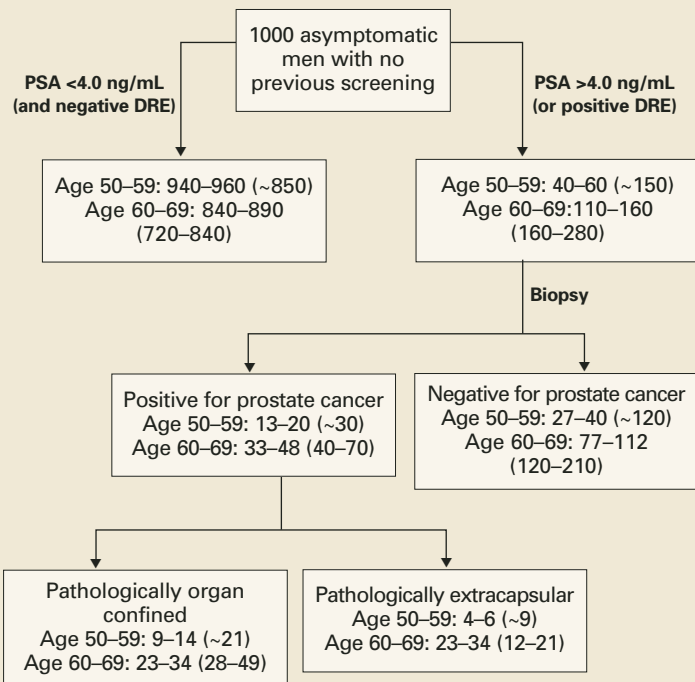
Aggressive screening not necessarily the reason. In the US, 2 geographic areas—Seattle, Washington and Connecticut—

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Men with low-grade tumors (Gleason score 2 to 4) have a minimal risk of dying from prostate cancer after 20 years

FIGURE 2

Yield of screening 1000 men for prostate cancer

Adapted from the Agency for Healthcare Research and Quality Systematic Evidence Review: Screening for Prostate Cancer.[4]

Benefits of screening

The benefit of any effective screening test is a decrease in the risk of the screened-disease mortality. The best way to demonstrate decreased risk is through a randomized controlled study of the screening test, and 2 such trials are underway for prostate cancer. In the meantime, a decision model estimates that aggressive treatment of organ-confined disease potentially adds 3 years of life for men in their fifties, 1.5 years for men in their sixties, and 0.4 years for men in their seventies (LOE: **2c**).[3]

Others have concluded that 25 men with clinically detected prostate cancer would need to be treated with surgery to prevent 1 prostate cancer death during a 6-year period, without evidence that quality of life is improved (LOE: **2c**).[43]

Consider quality of life. With uncertainty surrounding improvement in the *quantity* of life as a result of prostate cancer screening, improved *quality* of life may be an issue for patients. Focus group research has demonstrated that some patients believe it is better to know if a cancer is present than to wonder if it will be diagnosed when it is too late for cure.[44]

General quality of life has been found to be similar among men treated for prostate cancer and age-matched controls without prostate cancer; however, urinary, sexual, and bowel function vary substantially between treated and untreated men and by treatment type (LOE: **3b**) (**TABLE 2**).[45,46] In general, men treated with radical prostatectomy and brachytherapy often report better general quality of life than men who undergo radiation treatment, despite having more urinary and sexual problems (LOE: **2b**).[47,48]

Harms of screening

The chances of undergoing a biopsy based on an abnormal screening PSA are estimated at 15% to 40% depending on the patient's age (**FIGURE 2**).[3] There are adverse effects associated with transrectal biopsy of the prostate. In 2 large population-based

provided a natural experiment to compare the effect of aggressive screening on prostate cancer mortality (LOE: **2c**).[39] Although more aggressive screening and treatment took place in the Seattle area, prostate cancer mortality rates were similar to those in Connecticut over 11 years of follow-up. Similarly, in a study in British Columbia, prostate cancer mortality from 1985 to 1999 was not associated with the intensity of PSA screening (LOE: **2c**).[40]

Other possible explanations. If the mortality decrease is not related to PSA screening, what could cause it? One explanation is "attribution bias." Death certificate misattribution of cause of death from prostate cancer may partially explain the pattern of increasing, then decreasing mortality rates (LOE: **2c**).[41] Improvement in prostate cancer treatment, especially for advanced stage, and in particular hormone therapy, is another possible explanation for the decreasing prostate cancer mortality (LOE: **2c**).[14,42]

studies of screening, the most frequent complications were hematuria and hematospermia (LOE: **1b, 2b**) (**TABLE 3**), with more serious consequences such as sepsis and hospitalization occurring in fewer than 1% of patients. A study of 100 screened men with an abnormal PSA who underwent prostate biopsy found that although 69% felt moderate to severe pain with the biopsy, 80% would be willing to undergo a repeat biopsy (LOE: **1b**).[49]

Treatment options. If the biopsy result is positive, the most common treatment options for localized cancer—which represents over 80% of all prostate cancers diagnosed[6]—include radical prostatectomy, external beam radiation therapy, brachytherapy (internal radiation therapy) or expectant management (watchful waiting). Population-based studies have reported outcomes for these treatment options (**TABLE 2**). Outcomes derived from hospital-based series of other prostate cancer treatments, such as cryotherapy and 3-dimensional radiation, are available, but the estimates often reflect the experience of only a few hospitals and are not representative of other facilities. Androgen ablation is the standard treatment for metastatic prostate cancer.

Untoward effects of treatment. Approximately 60% of radical prostatectomy patients report some incontinence 12 months or more after surgery (LOE: **2b**),[50,51] and about 30% of patients need to wear pads for urine leakage (LOE: **2b**).[50–53] Men undergoing radiation therapy have less urinary incontinence, but about 30% complain of diarrhea and loose stools (LOE: **2b**).[51,52] Both therapies are associated with a high percentage of erectile dysfunction: approximately 60% of radiation therapy patients and 75% of surgery patients report their erections are not firm enough for intercourse (LOE: **2b**).[51,52]

Expectant management (following the cancer with regular PSA and ultrasound testing) is sometimes difficult to "sell" to patients whose fear of cancer dictates that the only logical response is to "cut it out."[44] A recent randomized trial indicated

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Useful websites for patients to find prostate cancer screening information

CENTERS FOR DISEASE CONTROL AND PREVENTION

www.cdc.gov/cancer/prostate/decisionguide/index.htm
10th grade reading level*
Good coverage of screening and treatment controversies
Offers downloadable PDF version

NATIONAL CANCER INSTITUTE

cis.nci.nih.gov/asp/FactSheetPub/AlphaSubList.asp?alpha=47
10th grade reading level
FAQ format
Offers Spanish version

AMERICAN CANCER SOCIETY

www.cancer.org/docroot/CRI/content/CRI_2_4_3X_Can_prostate_cancer_be_found_early_36.asp
12th grade reading level
Lacks discussion of treatment options and their side effects
Biased in favor of screening but acknowledges that other distinguished organizations are not

AMERICAN UROLOGICAL ASSOCIATION

www.urologyhealth.org/adult/index.cfm?cat=09
12th grade reading level
Easy to navigate among screening and specific treatment pages
Biased in favor of PSA screening

AMERICAN ACADEMY OF FAMILY PHYSICIANS

familydoctor.org/healthfacts/361/
11th grade reading level
Question/answer format
Very straightforward, lacks depth

www.aafp.org/x19519.xml
7th grade reading level
Separate information sheet for patients and physicians
Presents possible outcomes of PSA test and prostate cancer treatment in easy-to-follow format

WEBMD

my.webmd.com/medical_information/condition_centers/prostate_cancer/default.htm
9th grade reading level
Question/answer format
Specifically addresses false negative and positives with current estimates

DARTMOUTH CENTER FOR SHARED DECISION MAKING

www.dhmc.org/dhmc-internet-upload/file_collection/PSA.pdf
6th grade reading level
Well-designed, simple presentation of pros and cons of PSA testing

*Fleish-Kincaid grade level score based on average sentence length and average number of syllables per word.

> ### TABLE 5
>
> #### Talking points for patients and physicians
>
> Prostate cancer is an important men's health problem
>
> Screening may prevent early prostate cancer death
>
> DRE alone has little value as a screening test
>
> Age, prostate size, prostatitis, ejaculation, prostate biopsy, and prostate surgery can cause a falsely elevated PSA test
>
> Approximately 70% of men with an elevated serum PSA do not have cancer
>
> The percentage of PSA screening false negatives ranges from 10%–22% in large studies
>
> If the test is abnormal, a biopsy will be recommended
>
> If the biopsy is positive, treatment options will be given
>
> Many men experience long-term urinary incontinence and impotence related to their treatment

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Experts advise that men be fully appraised of the risks and uncertain benefits of prostate cancer screening to make an informed decision

that radical prostatectomy lowers prostate cancer mortality, local progression, distant metastasis, and overall survival as compared with watchful waiting over a median of 8.2 years of follow-up (LOE: **1b**).[54] However, these results may have little relevance to prostate cancer screening since only 5% of the cancers were screen-detected and 76% were palpable.

■ Recommendations from expert groups

Different expert groups have conflicting recommendations. Both the American Urological Association and the American Cancer Society recommend annual PSA screening starting at age 50 for most men; younger if risk factors are present. Groups that are evidence based tend to recommend a shared decision making process with patients. The AAFP and American College

of Physicians advise physicians to counsel men on the known risks and uncertain benefits of screening for prostate cancer. The US Preventive Services Task Force 2002 update concluded that evidence is insufficient to recommend for or against routine screening for prostate cancer using PSA or DRE. The National Cancer Institute cites a lack of evidence to determine a net benefit for PSA or DRE screening.

■ When will we know more?

Only 1 randomized controlled trial of prostate cancer screening has been completed[55]: 46,193 men were randomized to either PSA and DRE or no screening from 1989 to 1996. The study had methodological problems; for instance, only 23% of the group randomized to screening was screened. The investigators in the trial have interpreted its results as demonstrating a decrease in prostate cancer deaths in the screened group compared with the unscreened group (15 vs 48.7 per 100,000 man-years).[55] Others have criticized the statistical analysis and calculated the results using an "intent to screen" analysis, finding no difference in prostate cancer deaths between the 2 groups.[3,56]

Two randomized controlled trials of screening are ongoing: the National Cancer Institute's Prostate, Lung, Colon, Ovarian (PLCO) Screening Trial[57] and the European Randomized Study of Screening for Prostate Cancer.[58] Both were started in the mid-1990s and will not have results available for a few more years. Also underway is a randomized trial of intervention (radical prostatectomy) versus expectant management, called the Prostate Cancer Intervention Versus Observation Trial (PIVOT).[59]

■ Counseling recommendations

However, providing men with information on prostate cancer screening before they discussed it with their family physician, rather than after the visit, resulted in patients having a significantly more active

role in making a screening decision, and lower levels of decisional conflict (LOE: 2b).[61] Informational pamphlets are available through the AAFP and CDC websites listed in **TABLE 4**. Additional websites containing prostate cancer screening information are found in **TABLE 4**. We also provide a bullet item list of key points for discussion with patients (**TABLE 5**), which can be used along with the balance sheet provided here (**TABLE 2**).

Shared decision-making is not an easy or quick process. Yet, the majority of patients will benefit from the discussion, regardless of the final decision. Of course, there are instances when a shared decision-making process is well-documented, and still results in an undesirable outcome;[62] however, while the evidence for screening remains controversial, patients have the right to know that those controversies exist and why they exist. ■

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