

ACS Prostate Cancer Early Detection Recommendations: Update 2010





2010 ACS Guideline for the Early Detection of Prostate Cancer

The American Cancer Society recommends that asymptomatic men who have at least a 10-year life expectancy have an opportunity to make an informed decision with their health care provider about whether to be screened for prostate cancer, after receiving information about the uncertainties, risks, and potential benefits associated with prostate cancer screening.

Does screening for prostate cancer save lives?

Key Questions

- Does screening extend men's lives (are there benefits)?
- Does screening lead to health problems (are there harms)?
- Do the benefits outweigh the harms?

Does screening for prostate cancer save lives?

New Findings in Screening

Results from 3 major, long-term, randomized controlled trials (RCTs) were recently reported:

- European Randomized Study of Prostate Cancer (ERSPC)
- Göteborg (Swedish) Trial
- Prostate, Lung, Colon and Ovarian Trial (PLCO)



RCT results

ERSPC

Conclusion: 20% lower risk of prostate cancer death in the group invited to screening

Göteborg Trial

Conclusion: 40% lower risk of prostate cancer death in the group invited to screening

ERSPC and Göteborg

Additional Findings

- To prevent one prostate cancer death
 - Men screened: ERSPC 1410 / Göteborg 293
 - Men treated: ERSPC 48 / Göteborg 12
- Survival benefit first seen ~8 years after first screen
- Minimal to no participation of men of African origin and limited participation of men with family history
 - Relevance of findings to high risk men is unclear

PLCO

Conclusion: No mortality benefit among those invited to screening

Questions/concerns with study

- Prior screening
- Screening common in “usual care” arm
- Less than ½ of men with a positive screen result had a biopsy
- Insufficient participation of African Americans and men with + family history

Bottom line – no difference in death rates at 10 years between intensively screened and less-intensively screened men

Does screening for prostate cancer save lives?

- There is a higher rate of early stage detection, and prostate cancer death rates have fallen during the PSA era – but it is not clear that this is primarily due to screening
- Other possible reasons for this decline:
 - *Disease is found earlier because of increased awareness and use of diagnostic PSA testing*
 - *There have been substantial improvements in treatment for prostate cancer over the past 2 decades*

Is screening for prostate cancer associated with any harms?

Limitations of Screening

- False negative results
- False positive results
- Overdiagnosis
- Overtreatment

Limitations of Screening

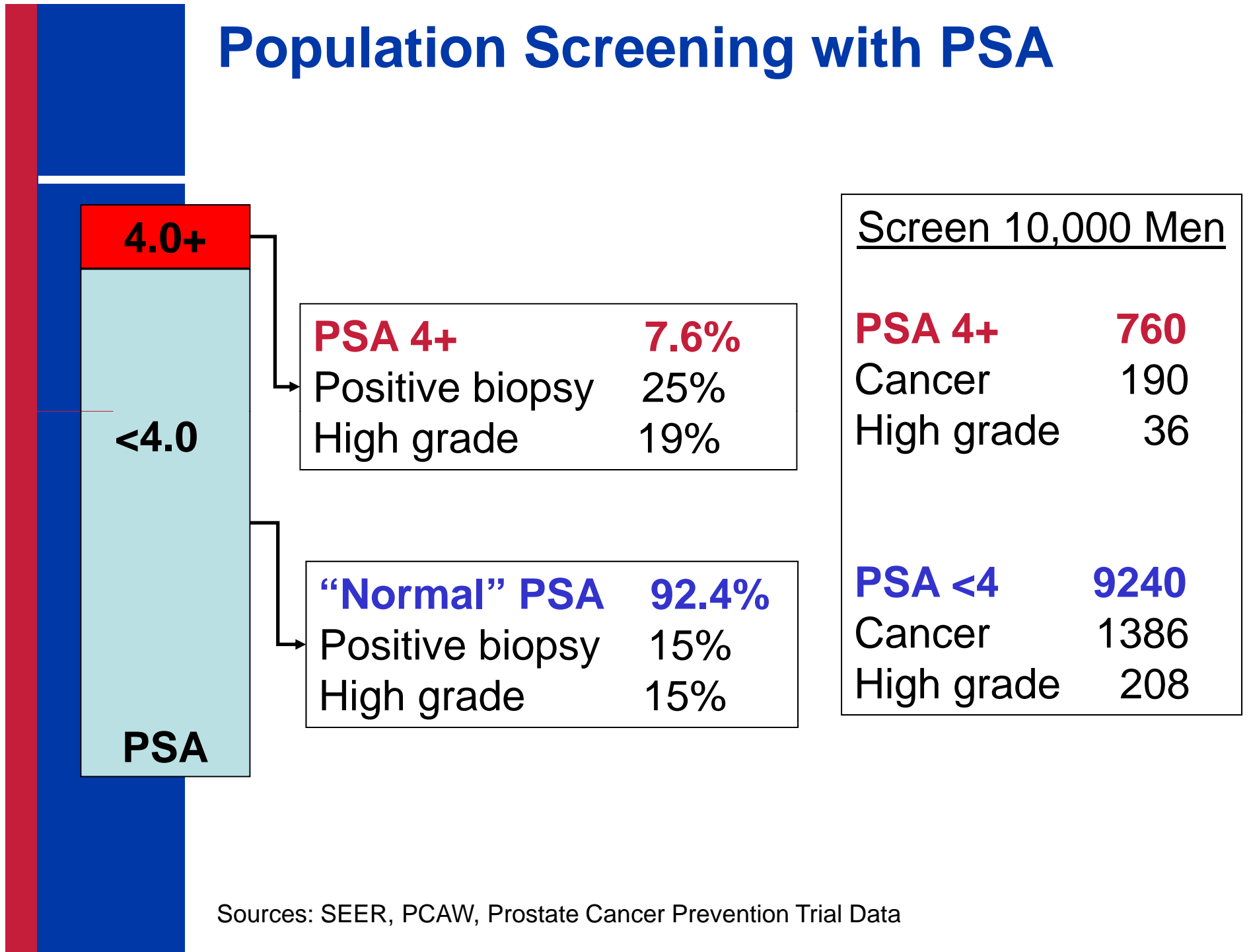
False negative results

- PSA and DRE “normal”, but cancer is present
- May lead to false reassurance and delayed diagnosis

Research has shown that no cut-off value of PSA is completely reliable to rule-out cancer

- End of study biopsies in the Prostate Cancer Prevention Trial found cancer in some men with PSA less than 1.0 ng/ml

Population Screening with PSA



Sources: SEER, PCAW, Prostate Cancer Prevention Trial Data



Limitations of Screening

False positive results

- PSA and/or DRE abnormal, but no cancer found
- Can lead to worry, unnecessary additional tests

False Positive Results

If 100 men in each age group are tested:

Age (in years)	# With PSA > 4.0	# With Cancer	# False Positives
50s	5	1–2	3–4
60s	15	3–5	10–12
70s	27	9	18

Limitations of Screening

Overdiagnosis

- Some cancers found by screening grow very slowly and will never cause harm.
- Estimates of screening-related overdiagnosis in the U.S.
 - Whites: 23 – 29%
 - African Americans: 34 – 44%

Sources: Etzioni 2002; Telasca 2008

Limitations of Screening

Overtreatment

- Overdiagnosis leads to overtreatment
 - Definition - treatment of cancer that, if undetected, would never cause harm
 - Estimates range from 20 – 40% in U.S.
- Treatment of prostate cancer can have life-altering complications and side effects

Frequency of Side Effects

Treatment	Side Effect	Frequency
Radical prostatectomy	• Erectile dysfunction	20–70%
	• Urinary incontinence	15–50%
External beam radiation therapy	• Erectile dysfunction	20–45%
	• Urinary incontinence	2–16%
Androgen deprivation therapy	• Sexual dysfunction	20–70%
	• Hot flashes	50–60%
	• Cardiovascular Dz	?
	• Diabetes	?

These complications may be a worthwhile trade-off for men whose lives are saved by treatment, but it is not clear how many men fall into this category.



Summary: Prostate Screening

Potential Benefits

- PSA screening detects cancers earlier.
- Treating PSA-detected cancers may be more effective, but this is uncertain.
- PSA may contribute to the declining death rate, but the extent is unclear

Potential Harms

- False negatives and false positives are common.
- Overdiagnosis and overtreatment are problems, but the magnitude is uncertain.
- Treatment-related complications and side effects can be significant.

Bottom line: Uncertainty about degree of benefits and magnitude of harms

Informed Decision Making is Recommended by all Major Organizations

	Recommendation
NCCN (2010)	<p><i>“Start risk and benefit discussion AND offer baseline DRE and PSA at age 40.”</i></p> <p><i>“There are advantages and disadvantages to having a PSA test, and there is no ‘right’ answer about PSA testing for everyone. Each man should make an informed decision about whether the PSA test is right for him.”</i></p>
AUA (2009)	<p><i>“The AUA is recommending PSA screening ... for well-informed men who wish to pursue early diagnosis.”</i></p> <p><i>“Patients need to be informed of the risks and benefits of testing before it is undertaken. The risks of over-detection and overtreatment should be included in this discussion.”</i></p>
USPSTF (2008)	<p><i>“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.”</i></p>

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The informed decision making discussion should begin:

- At age 50 for men who are at average risk of getting prostate cancer and have at least a 10-year life expectancy
- At age 45 for men at high risk of developing prostate cancer
 - African American men
 - Men who have a first-degree relative (father, brother, or son) diagnosed with prostate cancer at an early age (younger than age 65)
- At age 40 for men at even higher risk (those with several first-degree relatives who had prostate cancer at an early age)



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- Screening should not occur without an informed decision making process.
- Asymptomatic men who have less than a 10-year life expectancy based on age and health status should not be offered prostate cancer screening.



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- Men should weigh this information against their personal values and preferences when making a screening decision.
- Patient decision aids are helpful in preparing men to make a decision whether to be tested, and their use is encouraged.

2010 ACS Guideline: Decision Aids

Testing for Prostate Cancer



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What is my chance of having prostate cancer based on my PSA level?

If the PSA level is 4 or higher

Biopsy will find prostate cancer in
30 out of 100 men (30%).



- 😊 = man with no prostate cancer on biopsy
- 🟫 = man with prostate cancer on biopsy

If the PSA level is below 4

Biopsy will find prostate cancer in
15 out of 100 men (15%).



- 😊 = man with no prostate cancer on biopsy
- 🟫 = man with prostate cancer on biopsy

Decision Aids: Values and Preferences

What is important to you?

There are many reasons men decide to be tested or to not be tested for prostate cancer. Some reasons are listed below. Place a check by the reasons that are important to you.



Some reasons to be tested

Check what's important to you



I will have peace of mind when I know the test results.

I will know if I have prostate cancer or not.

I will have a better chance of getting cancer treatment if a cancer is found early.

Other reasons important to you (list them here):

over

✂ Cut out and take to your doctor.

What is important to you?

Some reasons not to be tested

Check what's important to you



I will worry about the test results.

I might find a prostate cancer that never would have caused me problems or shortened my life.

I will have to deal with treatment and its side effects.

Other reasons important to you (list them here):

Which way are you leaning about being tested?

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Want to be tested

Not sure

Do not want to be tested

✂

2010 ACS Guideline: Decision Aids

Supporting Organization	Type of Decision Aid	Title & On-line Access
American Cancer Society	Downloadable Document (PDF)	“Should I Be Tested for Prostate Cancer” Available at: www.cancer.org/prostatemd
Foundation for Informed Medical Decision Making	Video and On-Line Interactive Resource	“Is a PSA Test Right For You?” Available through Health Dialog at: www.healthdialog.com
Centers for Disease Control and Prevention	Downloadable Document (PDF)	“Prostate Cancer Screening: A Decision Guide” Available at: www.cdc.gov/cancer/prostate/pdf/prosguide.pdf “Prostate Cancer Screening: A Decision Guide for African Americans” Available at: www.cdc.gov/cancer/prostate/pdf/aaprosguide.pdf “La Detección del Cáncer de Próstata: Una Guía para Hispanos en los Estados Unidos” Available at: www.cdc.gov/cancer/prostate/pdf/prostate_cancer_spanish.pdf
Mayo Clinic.com	On-Line Resource	“Prostate Cancer Screening: Should you get a PSA test?” Available at : www.mayoclinic.com/health/prostate-cancer/HQ01273
University of Cardiff, U.K.	On-Line Interactive Resource	“PROSDEX: A PSA Decision Aid” Available at: www.prosdex.com

Source: Wolf , et al. CA, 2010.



2010 ACS Guideline for the Early Detection of Prostate Cancer

Guideline also includes:

- Core elements of a decision making discussion
- Guidance regarding community-based screening events
- Recommendations for men who choose to be screened
- Individualized risk assessment



For Men Who Choose to be Screened

After learning about the potential benefits and known limitations of screening for prostate cancer, if a man decides to be screened:

- Screening should be done using the PSA blood test
- DRE is optional (at the discretion of the man and his clinician)

For Men Who Choose to be Screened

Updated recommendations on referrals and rescreening intervals:

- < 2.5 ng/ml - repeat screening can be safely extended to every 2 years
- 2.5 to 3.9 ng/ml - rescreen annually; consider DRE; perform individualized risk assessment
- ≥ 4.0 ng/ml - consider referral for further evaluation and/or biopsy

Individualized Risk Assessment for Men with PSA Levels of 2.5 – 4.0 ng/ml

- Factors that influence the risk of prostate cancer:
 - African American race
 - Family history of prostate cancer
 - Increasing age
 - Abnormal digital rectal exam
 - Prior negative prostate biopsy lowers risk
- A Web-based risk assessment tool merges this information to estimate a man's overall risk of prostate cancer and, more specifically, his risk of high-grade prostate cancer.
 - This tool is available on-line at <http://deb.uthscsa.edu/URORiskCalc/Pages/uroriskcalc.jsp>

Research Needs

New screening and diagnostic tools that:

- Detect cancers, but not benign disease
 - Serum, tissue, and urine markers are all under evaluation
- Distinguish aggressive, dangerous prostate cancers from slow-growing, low risk forms.

Treatment enhancements:

- New treatments with lower morbidity
- Better application of existing treatment modalities resulting in enhanced quality of care and more uniform outcomes

2010 ACS Guideline: Supporting Materials and Information

Updated materials for clinicians and patients are available at

www.cancer.org/prostatemd

- Patient decision aid: “Should I Be Tested for Prostate Cancer”
- Brochure: “What You Should Know About Prostate Cancer Testing”
- Prostate Cancer Fact Sheet
- Cancer Facts for Men
- Cancer screening exam room wall chart
- Links to decision aids from other organizations
- Link to ACS guidelines article and evidence review



Thank You!
