

DECISION AID TOOL

PROSTATE CANCER SCREENING WITH PSA TESTING

This booklet is what is often called a decision aid. The goals of a decision aid are to help people better understand their medical choices and to help them make the best medical decision possible for their situation.

This decision aid is for men who are concerned about prostate cancer and are trying to decide whether or not to receive a blood test, known as the prostate-specific antigen (PSA) test that is used to screen for prostate cancer. PSA-based screening is often used to screen healthy men for prostate cancer, and may be included as part of a routine check-up. The PSA test can be done with or without other tests such as a digital rectal exam. Visit www.cancer.net and/or ask your doctor for more information about other tests to screen for prostate cancer.

The goal of this decision aid is to help men and doctors make shared and informed decisions about prostate cancer screening. It is based on recommendations from Screening for Prostate Cancer with Prostate-Specific Antigen Testing: American Society of Clinical Oncology Provisional Clinical Opinion. Use of this decision aid is voluntary.

The decision aid is divided into two sections:

1. Learning the risks and benefits of your options, with your doctor.
2. Help for thinking through the decision, on your own.

The first time you read this decision aid, your doctor or nurse should be available to help you understand the information, and any family members or friends you would like to include. You may also take this document home after reviewing it with your doctor or nurse.

This guide contains numbers or statistics which may predict the course of prostate cancer. If you are not comfortable with this type of information, you may prefer not to use this decision aid.

What role do you prefer in making this choice?

- I prefer to share the decision with _____
- I prefer to decide myself after hearing the views of _____
- I prefer that someone else decides
- I prefer to decide on my own

If help is desired, from whom?

- Doctor Children Other person
- Spouse/Partner Other family member(s) _____

This practice tool for physicians is a decision aid derived from an ASCO® provisional clinical opinion. The provisional clinical opinion and this decision aid are not intended to substitute for the independent professional judgment of the treating physician. Provisional clinical opinions do not account for individual variation among patients and may not reflect the most recent evidence. This decision aid does not recommend any particular product or course of medical treatment. Use of the provisional clinical opinion and this tool is voluntary. The full provisional clinical opinion and additional resources are available at www.asco.org/pco/psa.

THE BOTTOM LINE

This decision to get PSA tested is not a simple one.

Weighing the possible benefits against the possible risks is important. It is ultimately up to each man, after hearing all the information from their doctor.

The main benefit of PSA testing is that for some men it leads to the identification and treatment of harmful prostate cancer earlier when treatment is more effective.

The main risk of PSA testing is that for some men it leads to additional invasive tests, treatments, and side effects that turn out to be unnecessary. This is because some prostate cancers detected would never have caused a problem in their lifetimes.

Most PSA tests come back as normal and this knowledge can provide peace of mind around your risk of having prostate cancer. It's important to think about what you will do if your PSA level comes back as suspicious for prostate cancer. If it does, you and your doctor will talk about this, along with risk factors for prostate cancer some men have. These include age, family history of prostate cancer, race and having urinary symptoms.

Think about not only the blood test, or possible biopsy (doctors removing tissue from your prostate to test it for cancer) that could come next, but also the possible treatments if prostate cancer is found.

If you have a raised PSA, a biopsy will likely be recommended.

The raised PSA doesn't automatically mean you have prostate cancer; in fact most biopsies will show that there is no prostate cancer.

The main benefit of a biopsy is that it can either rule out prostate cancer or identify higher-risk (more harmful) prostate cancer earlier when treatment may be more effective.

The main risk of a biopsy is that it can identify the lower-risk (less harmful) kind of prostate cancer that may not cause health problems in a man's lifetime.

It is important to consider that not all lower-risk prostate cancers automatically require treatment. Carefully watching instead of treating right away, known as active surveillance, is a reasonable option for some men.

There are tools your doctor can use to better estimate your risk of having prostate cancer—the PSA value is one piece of information that is used. This may help you decide whether or not to get a biopsy.

Think about what is most important to you, including how old you are and whether or not you have health problems, and what you would do if your PSA level was raised after having a PSA test.

INTRODUCTION

The PSA test itself is simple. It is a blood sample that can be collected as part of a routine check-up at the doctor's office. The PSA test checks for raised PSA levels in the blood.

Raised PSA levels

- Raised PSA levels are suspicious and could mean prostate cancer
- They could also be raised for other reasons other than prostate cancer
- The higher the PSA level the greater the concern that there might be prostate cancer and the chance a biopsy will be recommended
- As a result PSA screening for prostate cancer is a hot topic.

Lower or regular PSA levels

- The lower the PSA level, the lower the risk of prostate cancer, and especially of unhealthy/high-risk prostate cancer
- If you have regular levels of PSA, it doesn't automatically mean you don't have prostate cancer
- There is no level of PSA that guarantees a man does not have prostate cancer¹

THE OPTIONS AFTER RAISED PSA LEVELS

- Think about: If I get a PSA test done, what will I do if my PSA level comes back as suspicious for prostate cancer?
- Options include: do nothing, check PSA again after a little while, or have a prostate biopsy

Doing nothing

- If you choose to do nothing and if it turns out later that it is prostate cancer, it may be the kind that is slow growing and doesn't usually cause problems for men in their lifetimes, especially if they are older or have other serious medical conditions. Or, it could be the kind of prostate cancer that grows more quickly and can cause serious problems, including death, if not caught early and treated. (Some prostate cancers can cause serious problems, including death, even if they are caught early and treated.)

Checking PSA again after raised PSA levels

- If you choose to check PSA again later, the test may come back with lower levels, the same levels, or higher levels of PSA. If lower, that's a good sign that there may not be prostate cancer. You may want to have it checked again to see if it stays low. If the levels are the same or higher, the choices are the same as before.

Having a biopsy

- A prostate needle biopsy involves removing and testing cells from your prostate gland. It is generally safe. But, it is a test that invades your body and can cause fever and infection in a small number of men. If the prostate biopsy does find prostate cancer you will have more decisions. The pros and cons of prostate cancer treatment are not part of this decision aid. But, men who get treatment for prostate cancer fall into one of three groups: those whose lives were saved by the treatment, those who were treated unnecessarily because their cancer would never have gotten worse even without treatment, and men whose cancer comes back and gets worse even with treatment.

The choices about PSA testing for prostate cancer screening could have a big impact on men's lives. This is why the choice to have a PSA test is an important decision that men should know about and consider carefully with their doctors.

Below, the Decision Aid explains the parts of the decision in detail. It describes the possible benefits, such as lowering the risk of dying from prostate cancer and the possible risks, such as unnecessary tests or treatments.

¹ Thompson IM, et al., Prevalence of Prostate Cancer among Men with a Prostate-Specific Antigen Level ≤ 4.0 ng per Milliliter *N Engl J Med* 2004;350:2239-46.

BENEFITS AND RISKS OF PSA TESTING

Introduction to benefits and risks

The information described in this decision is from one study called the European Randomized Study of Screening for Prostate Cancer (ERSPC). The study included 162,388 men, aged 55 to 69 years, who were followed by researchers for 11 years. Half of the men received 2 to 3 PSA tests during that time and half of the men did not get the PSA tests.

In this study, men who had a raised PSA higher than a certain level ($> 3\text{ng/ml}$) usually had a biopsy. It is important to note that there is no one set level of PSA to tell us when a biopsy is needed, but usually the higher the amount of PSA in the blood, the more the need for a biopsy to see if it is prostate cancer.

The numbers in this decision aid show the benefits and risks, after 11 years of follow-up on average, for men in this study.

BENEFITS

What is the main potential benefit of having a PSA test?

The main possible benefit to getting a PSA test is to find a prostate cancer that would ultimately cause harm, or cause death, when treatment could potentially cure it.*

This Decision Aid includes pictographs to show the differences between men who had the tests and men who did not. Each pictograph contains 1000 squares. Each square is equal to 1 person.

The numbers in the charts reflect an average risk of dying from or being diagnosed with prostate cancer from the study described above. The chances, for you, may be either higher or lower, based on the stage of the cancer and other clinical factors (such as age and other health conditions).

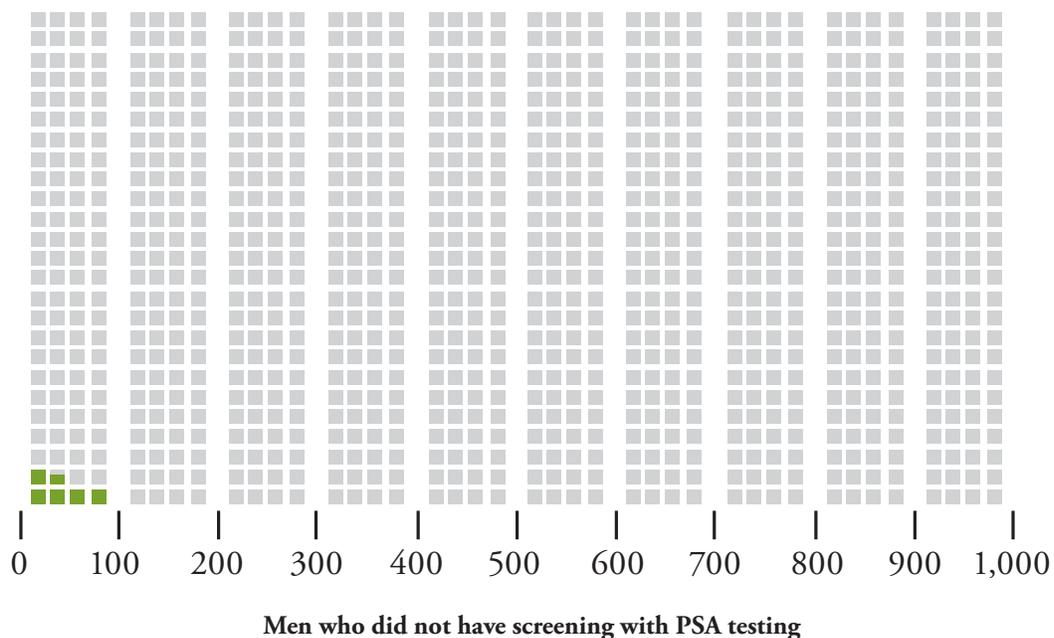
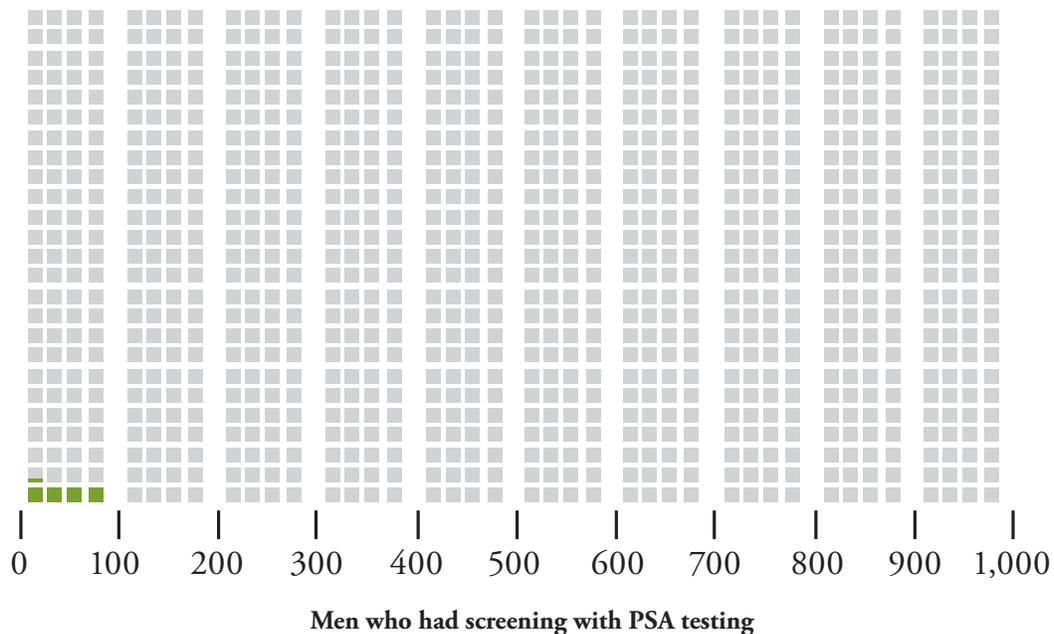
* But, it is difficult to predict for an individual man whether treatment of a prostate cancer found through screening will lead to this benefit.

The first set of pictographs, below, show the chances of chance of dying of prostate cancer. These numbers are from the men in the study over an 11 year period.

Effect of having PSA test on death from prostate cancer

Out of 1000 men who had screening, about 4 died of prostate cancer. Out of 1000 men who did not have screening, about 5 died of prostate cancer.

There were about 20% fewer prostate cancer deaths in the men who had PSA screening.²

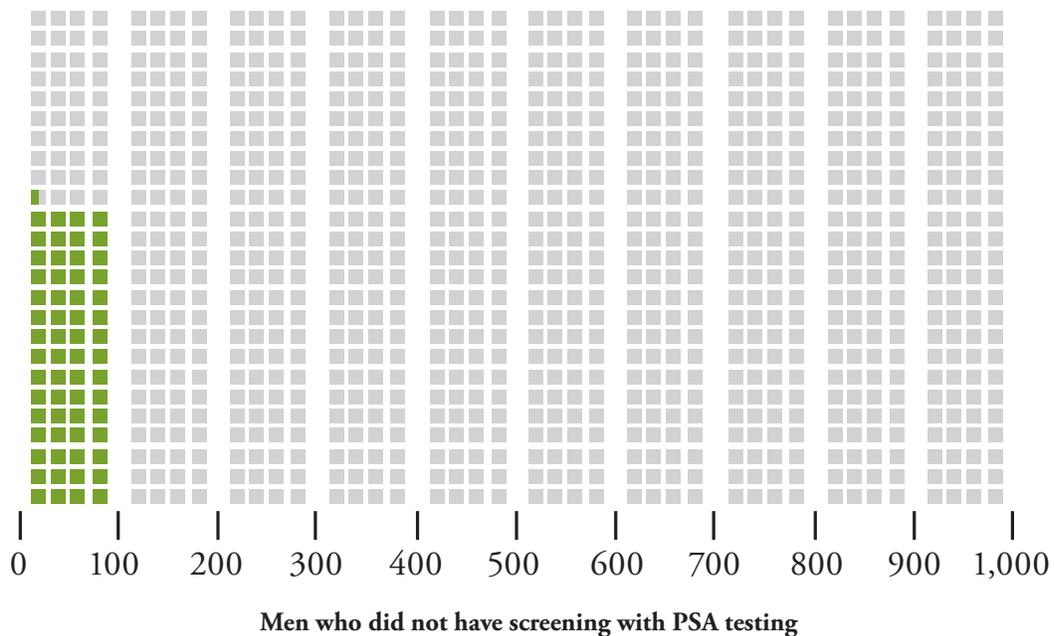
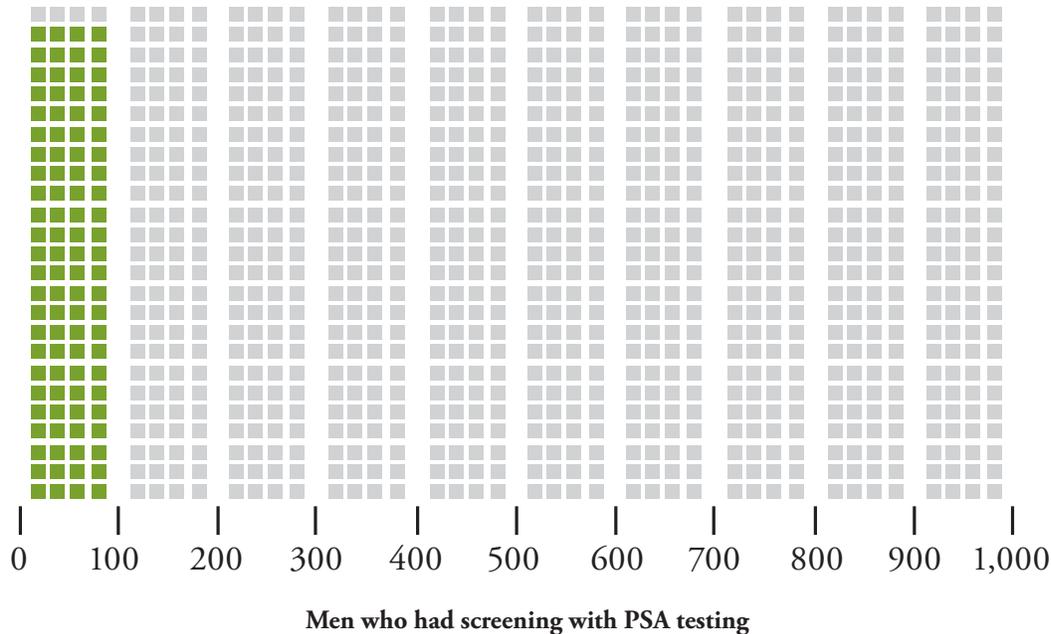


² Schröder FH, Hugosson J, Roobol MJ, et al. Prostate-cancer mortality at 11 years of follow-up. *N Engl J Med.* 2012;366(11):981-90.

This set of pictographs show the chances of finding out you have prostate cancer.

Chances of being diagnosed with prostate cancer if you have a raised PSA test and a biopsy

Out of 1000 men who had screening, about 96 cases of prostate cancer were found. Out of 1000 men who did not have screening, about 60 cases of prostate cancer were found.



The graphs above mean that screening catches more cases of prostate cancer. By not screening, less cases of prostate cancer are caught. Some of these additional prostate cancers would be the more harmful kind that needs treatment. But, others would be the less harmful kind that would not have caused harm or death over a man's lifetime.

RISKS

What is the main potential risk of having a PSA test?

The main potential risk with PSA testing is that raised results, plus a biopsy, may detect the kind of less harmful prostate cancer that leads to treatment (and its side effects) that wasn't necessary.

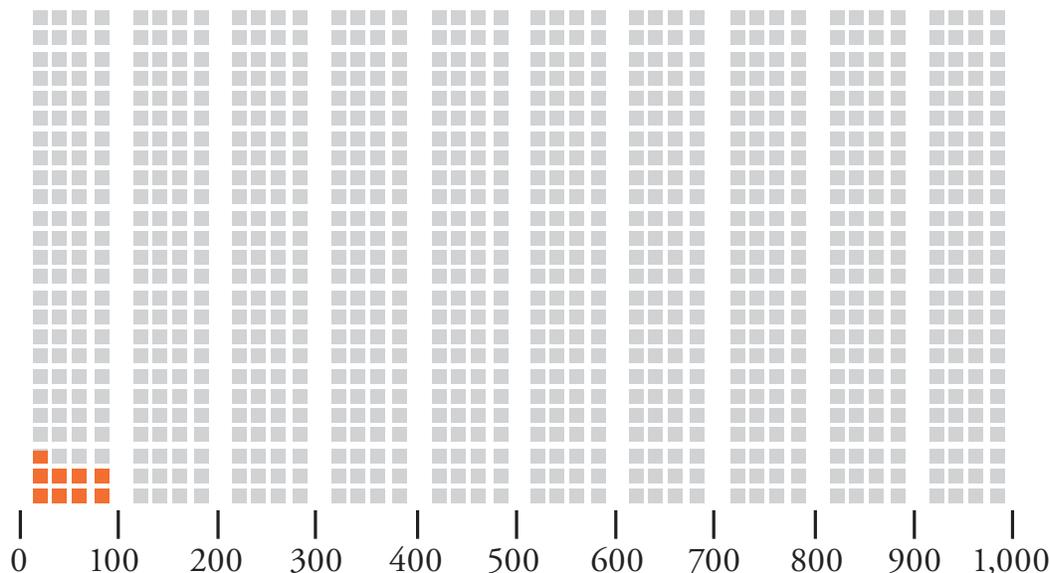
1. From the PSA test, one common risk is having a false positive test. This means that the PSA test was "positive" (the PSA level was raised enough to raise suspicion of prostate cancer) but that the needle biopsy was negative. Approximately 1 out of 3 positive PSA tests turn out to be false positives.*³
2. From the biopsy, in a small number of men, there can be side effects. The side effects are generally manageable, but in the case of false positive PSA tests, those side effects could have been avoided. Side effects can include serious infection or fever leading to hospitalization, or short-term bleeding in the urine or sperm, or trouble urinating.
3. If the prostate biopsy does detect prostate cancer, it may be a kind of prostate cancer that wouldn't be a problem in your lifetime (overdiagnosis). It may be the slow growing kind of prostate cancer. In those cases, the treatment, and the side effects of treatment, wouldn't have been needed (overtreatment).

The pictographs below show the chance of having some of the common potential risks with a raised PSA leading to a biopsy. The numbers in the charts reflect an average risk from the study described above. The chances, for you, may be either higher or lower.

Hospitalization⁴

About 9 men out of 1000 who had a biopsy after a raised PSA were hospitalized for inflammation and/or infection of the prostate.

Note: results of another study, with 75,000 men, showed more men being hospitalized than in the past. In 1996, 1% of the men were hospitalized, compared to 4% in 2005.



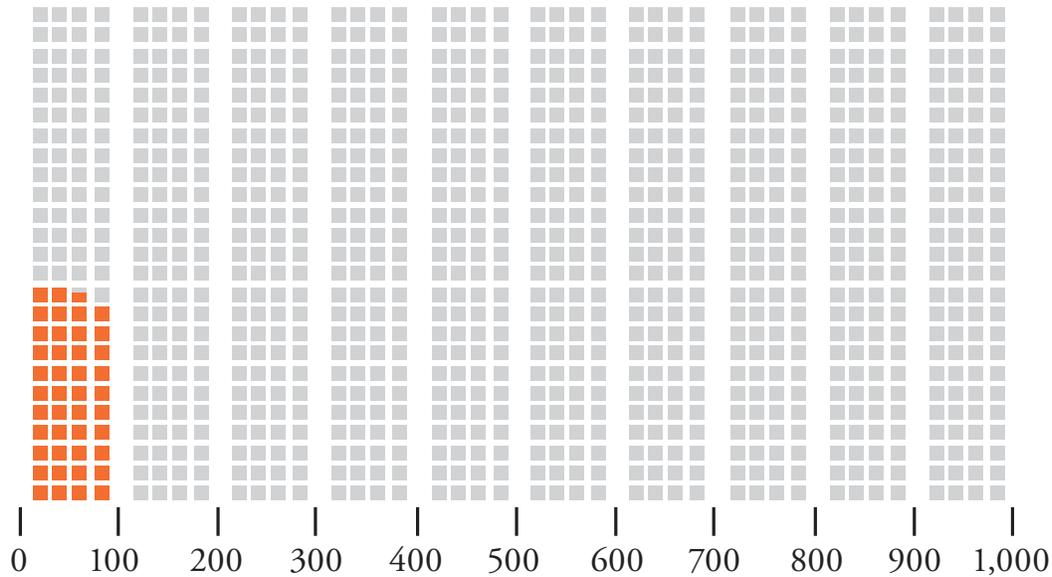
* Of about 20,000 men who had biopsies, about 35% were found to have prostate cancer and 65% were found not to have prostate cancer.

³ Ibid.

⁴ Loeb S, van den Heuvel S, Zhu X, et al. Infectious Complications and Hospital Admissions After Prostate Biopsy in a European Randomized Trial. *Eur Urol.* 2012 Jan 5. [Epub ahead of print].

Fever

About 42 men out of 1000 who had a biopsy after a raised PSA had a fever.



Additional side effects

Some men get other side effects. They can include short-term pain, bleeding in the urine or sperm, or trouble urinating. If a man is treated for prostate cancer, there can be serious side effects (this tool does not discuss treatment options). You can ask your doctor more about the side effects of biopsy and of prostate cancer treatment.

Which men do ASCO experts recommend do or do not have PSA testing?

Testing for PSA can be done as part of your routine blood work. For men expected to live 10 or less years, ASCO does not recommend a PSA test because overall it is more likely to be harmful than helpful. For men expected to live more than 10 years, the experts recommend that you think about the pros and cons of screening and consider your values and preferences around issues like biopsies and treatment if the results come back as suspicious for cancer.

WEIGHING YOUR OPTIONS

The following pages are to help you think about PSA testing as part of prostate cancer screening after you have talked to your doctor. You may want to do this on your own or with someone else (for example, family, friends, or other caregivers outside of the doctor's office).

Your test options include:

1. getting PSA testing now,
2. getting PSA testing later, or
3. not getting PSA testing.

If PSA is raised, then options include:

1. repeat PSA testing,
2. getting a biopsy, or
3. not getting a biopsy.

The next two pages include three steps:

1. What decision do you need to make?
2. What information and help do you need to make the decision?
3. What are the next steps?

1. What decision do you need to make?

How soon do you want to make a choice? _____

2. What information and help do you need to make the decision?

Do you know the benefits and risks of each option? _____

If not, what information do you need? _____

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Which benefits and risks *matter most* to you (please see table below)?

- In the following table, use the numbers to show how important each benefit and risk is to you.
- If you circle the number five, then the risk or benefit matters most. If you circle zero, then the risk or benefit matters least.
- Finally, make a star or asterisk (*) in the column next to the benefit and/or risk(s) that you think are most likely to happen or are most worried about.

	How much does this matter? Please circle a #: [0 (none) —5 (a lot)]	How likely is this to happen to you? [0 (none) —5 (a lot)]
Potential benefits of PSA testing (including a biopsy):		
Ruling out if you have prostate cancer	0 1 2 3 4 5	0 1 2 3 4 5
Finding higher-risk prostate cancer earlier when treatment may be more effective	0 1 2 3 4 5	0 1 2 3 4 5
Reducing your risk of dying from prostate cancer	0 1 2 3 4 5	0 1 2 3 4 5
Potential risks of PSA testing (including a biopsy):		
From a raised PSA:		
Getting a prostate biopsy when you do not have prostate cancer	0 1 2 3 4 5	0 1 2 3 4 5
From Prostate Biopsy:		
Identifying prostate cancer that may not have been a problem in your life time	0 1 2 3 4 5	0 1 2 3 4 5
Infection	0 1 2 3 4 5	0 1 2 3 4 5
Fever	0 1 2 3 4 5	0 1 2 3 4 5
Short-term trouble urinating	0 1 2 3 4 5	0 1 2 3 4 5
Potential benefits of not having a PSA test		
Avoiding overdiagnosis and overtreatment	0 1 2 3 4 5	0 1 2 3 4 5
Not having to make a decision about having a biopsy if PSA is raised	0 1 2 3 4 5	0 1 2 3 4 5
Not having a biopsy and its potential side effects, in cases where the PSA is raised, but there is no prostate cancer	0 1 2 3 4 5	0 1 2 3 4 5
Potential risks of not having a PSA test		
Not finding out if you may have high-risk prostate cancer when it is still potentially curable	0 1 2 3 4 5	0 1 2 3 4 5
Other	0 1 2 3 4 5	0 1 2 3 4 5

Do you have enough facts to make a choice? _____

If not, what more would you like to know? _____

Do you have enough support and advice from other people to make a choice? _____

If not, who do you want to talk with before making your decision? _____

Are you choosing your treatment option without pressure from others? _____

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3. Plan the next steps

Consider planning your next steps based on your needs:

- a. If you feel you do not have enough support and/or if you feel pressure from others—you may want to look for other support. Your doctor, hospital, or clinic may be able to refer you to others who could help you find additional support.
- b. If you feel you do not have enough facts about PSA testing and/or prostate cancer, you may want to get more. For example, you could visit cancer.net (www.cancer.net). Other groups have also created other resources.

4. In the following space, write down any additional other concerns and/or issues that you think are important to your decision (for example, other health issues, your age, money issues, family, etc.):

OTHER RESOURCES

Prostate Cancer Risk Calculators for the General Population

1. Prostate Cancer Prevention Trial (PCPT) Prostate Cancer Risk Calculator
 - <http://prostatecancerinfolink.net/risk-prevention/pcpt-prostate-cancer-risk-calculator/>
 - <http://deb.uthscsa.edu/URORiskCalc/Pages/uroriskcalc.jsp>
2. Sunnybrook Nomogram–based prostate cancer risk calculator (SRC)
 - www.prostaterisk.ca
3. European Randomised Study of Screening for Prostate Cancer (ERSPC) Risk Calculator
 - www.prostatecancer-riskcalculator.com/en/prostaatwijzer_vooraf.html

Screening for Prostate Cancer

1. American Cancer Society. Testing for Prostate Cancer: “Should I be tested? Is this the right choice for me?”
 - www.cancer.org/acs/groups/content/@nho/documents/document/acspc-024618.pdf
2. CDC. Prostate Cancer Screening: A Decision Guide (also one specific to African-American men) 2006 pdf decision guides
 - www.cdc.gov/cancer/prostate/basic_info/screening.htm
3. Health Dialog. Is a PSA test right for you? 2011 web booklet and videos
 - www.healthcrossroads.com/example/crossroad.aspx?contentGUID=fc326615-5b29-47f1-87c3-9a3e2d946919
4. Prosdex. University of Cardiff. 2005 online resource
 - www.prosdex.com/index_content.htm
5. Healthwise—Prostate cancer screening: Should I have a PSA test? 2010 decision aid
 - www.healthwise.net/cochranedecisionaid/Content/StdDocument.aspx?DOCHWID=aa38144
6. Mayo Clinic—Prostate cancer screening: Should you get a PSA test? 2011
 - www.mayoclinic.com/health/prostate-cancer/HQ01273
7. USPSTF: How to Talk with Your Patients When Evidence Is Insufficient. 2008 Short Video
 - www.uspreventiveservicestaskforce.org/uspstf/uspSprca.htm