AD_____

Award Number: W81XWH-06-1-0182

TITLE: Internet-Based Education for Prostate Cancer Screening

PRINCIPAL INVESTIGATOR: Kathryn L. Taylor, Ph.D.

CONTRACTING ORGANIZATION: Georgetown University
Lombardi Comprehensive Cancer Center
Washington, DC 20007

REPORT DATE: December 2007

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
01-12-2007	Annual	1 Dec 2006 – 30 Nov 2007

4. TITLE AND SUBTITLE

Internet-Based Education for Prostate Cancer Screening

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-06-1-0182

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Kathryn L. Taylor, Ph.D.

Email: taylorkl@georgetown.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Georgetown University
Lombardi Comprehensive Cancer Center
Washington, DC 20007

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Prostate cancer (PCa) is the leading cancer diagnosis among men and the second leading cause of male cancer death. However, screening asymptomatic men remains controversial, as early diagnosis and treatment of PCa has not yet demonstrated reduced disease-related mortality in a randomized trial. The goal of the current study is to develop and assess widely accessible, easily disseminable methods to assist men in making informed decisions about PCa screening. We will compare the efficacy of a new web-based, interactive decision support approach to our existing print-based PCa screening decision tool, among a diverse sample of male primary care patients. Abundant evidence documents the expanding role of the Internet in increasing access to and understanding of health information and the need for systematic evaluations of Internet-based interventions. The print- and web-based interventions have been completed and we have accrued 65 participants to the randomized trial.

15. SUBJECT TERMS
Prostate Cancer Screening, Medical Decision Making, Education and Communication

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
U	U	U	UU	48	USAMRMC

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

INTRODUCTION

Prostate cancer (PCa) screening is controversial, as early diagnosis and treatment of PCa has not yet demonstrated reduced disease-related mortality in a randomized trial.[1,2] The primary question is whether PCa screening results in overdiagnosis, the detection and treatment of disease that would not otherwise result in increased morbidity or mortality. The Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial[3] is designed to address this question, but results will not be available for at least 10 years. At present, the lack of evidence for effectiveness and the resulting controversy have not deterred PCa screening, as the practice of screening asymptomatic men is increasing in the U.S.[4-6] Most men who undergo PCa screening are not making fully-informed decisions, as they are unaware of the controversy and believe that the medical community unequivocally accepts the benefits of screening.[7-9] This issue is not unique to PCa as the difficulty of making medical decisions prior to the availability of definitive outcome data has been a long-standing issue in cancer screening.[10,11] Importantly, this issue is likely to become increasingly significant as screening technology advances more rapidly than our ability to validate it.[11-15] Thus, widely applicable approaches to health education are needed in order to facilitate informed decision making about the growing number of unproven treatment and screening technologies.[16-17] The goal of the current study is to develop and assess a widely accessible and disseminable method to assist men in making informed decisions about PCa screening.

Specific Aims: 1) Evaluate the impact of the delivery method (Web vs. Print vs. Usual Care) on the key patient outcome variables of knowledge, decisional satisfaction, health-related quality of life (HRQL), and the screening decision. 2) Assess factors that moderate the interventions' impact on the primary outcomes, including commitment to screening (defined by screening history and decisional balance), computer literacy, and age. In exploratory analyses, we will evaluate baseline factors that are related to use of the website by tracking the topics accessed and the amount of information reviewed. Study Design: In Phase I (months 1-6), we will develop an interactive, Internet-based, patient information and decision aid. In Phase II (months 7-36), we will evaluate the impact of this decision aid in a randomized controlled trial with male primary care patients aged 45-70 (N = 600). Trial arms include: 1) print-based information and decision aid (Print), 2) web-based information plus interactive decision aid (Web), and 3) usual care (UC). Subjects will complete outcome assessments at baseline, 1- and 12-months post-baseline. Relevance: This research has the potential to make several significant and innovative contributions: 1) the development and evaluation of a widely-disseminable method of educating a heterogeneous group of patients about a controversial topic, which can be adapted for other similarly contentious issues, 2) a determination of whether Web based materials are a feasible method of patient education for this age cohort, compared to print materials, 3) a determination of who among the target population benefits the most from a web-based intervention, and 4) the information required to streamline and target future web-based educational interventions.

BODY

We have completed a number of tasks, including redesign and completion of the booklet, completion of the website, completion of the subject tracking database, completion of a feasibility study, completion of a study of physician attitudes, knowledge and practices regarding prostate cancer screening, and the randomized trial is underway. Participant accrual for the trial has begun and we currently have accrued 65 active participants with a 41% participation rate. We anticipated a 50% participation rate in our calculations of accrual feasibility and are working toward increasing the participation rate using number of measures, described in Plans section below. Thirty-two one-month assessments have been completed, with a 97%% completion rate of those who are currently due to be completed.

Development of the Booklet. As we noted in our annual report last year, our consultants, experts in prostate cancer screening (Steven Woolf, M.D., and Alex Krist, M.D.) and health communication (Janet Ohene-Frempong, M.S.), all suggested significant modifications to our existing print booklet. This is the booklet that we tested in our study on prostate screening that began in 2004. We were not planning on needing to change it significantly and therefore had not allotted the time on the grant for this. However, their suggestions were very good and we felt it would be a mistake to ignore them. As a result, we spent three months holding meetings, rewriting the booklet, sending it to our consultants and research team members for edits, all in an iterative process. The development of the website could not occur

simultaneously with the rewriting of the booklet, as the content of the print and website had to be consistent. As a result of these events, we are several months behind our intended schedule, but expect that we will be able to make up this time now that accrual has begun.

Individual interviews and focus groups were held with men from April 2007 through June 2007 (N=14 men). Men were accrued from Georgetown University, the Washington Hospital Center, and a local center for GED preparation (in order to insure that we had low literacy men represented in our focus groups). We modified the materials based on their feedback, including the wording of the decision aid items. The quantitative ratings of the booklet and website were positive, including the percent who thought that the materials were clear (85%-93%) and that it helped them to explore the benefits and limitations of screening (71%-92%). The final booklet is 35 pages long and includes facts about the prostate gland, information about screening, facts about treatments, risk factors, symptoms of prostate cancer, epidemiology of the disease, questions to ask your doctor, a 10-item decision aid framed in a decisional balance format, glossary, selected references, and contact information for national organizations. Please see attached PDF of the booklet.

Website development. Once the booklet was close to its final version, development of the website began. We sent the revised booklet to our web developer (Triad Interactive) to incorporate all the changes we had made in the booklet into the website. Based on the feasibility study we conducted last year of men's computer/Internet access and their willingness to participate in an Internet-based study (see last year's annual report), we elected to develop a website intended for broadband users, as opposed to dial up users. Triad gave us several versions of the website to review throughout early 2007. We made the decision to add 8 video testimonials to the website, which we had not planned in the grant submission. This represents a significant enhancement to the website, but also slowed down our timeline by approximately two months. The testimonials represent 4 pros and 4 cons of screening, and are paired next to each other to encourage men to review both sides of the issue. Further, at the very beginning of the website, men are asked to classify their screening behavior (on a 4 point scale), and men who are pro screening are automatically sent to the con testimonial, and men who are not pro screening are sent to the pro screening testimonial. This is an effort to insure that men do not only read what matches with their prior understanding and beliefs about prostate cancer screening.

By May, 2007, audio was added to each page of the website, the decision aid was implemented, and nearly all of the content was available on the website. Edits were made and the final website was tested and then completed in August 2007. Individual interviews and focus groups (N=14 men) were also held for the website in June and July 2007 and changes were made regarding technical issues on the website and directions about how to use the website. The address of the website is www.prostatedecision.org and the Username is Guest and the Password is Guest1235.

One feature of the website is the capability to track the pages on the website each subject accesses and how much time is spent on each page. This will provide important information regarding which sections appear to be the most beneficial with regard to improvements in understanding the issues surrounding screening. In addition, we can see that those men who have been assigned to the web condition have accessed it, confirming their self-reports that we obtain during the one-month follow-up interview.

Physician Study. Prior to beginning the PCSEd randomized trial, we conducted a cross-sectional survey of the primary care physicians at the two academic medical centers from which patients will be recruited for the randomized trial. The goal of this ancillary study was to examine the physicians' attitudes and practices regarding prostate cancer screening prior to the start of the trial. Understanding what factors may influence their discussions about the risks and benefits of PCa screening as well as practices and recommendations to their patients may aid in the interpretation of the findings from the trial. Additionally, we sought to determine the impact of physician rank (attending, resident, or intern) on screening knowledge and practice. Participants were primary care physicians at Georgetown University Hospital (N = 51) and the Washington Hospital Center (N = 47). The overall response rate across both sites was 83%. Ninety-eight physicians returned completed questionnaires (16.3% were attendings, 42.9% were residents, and 39.8% were interns). Surveys assessed beliefs about prostate cancer screening, factors that influence screening practices, and preferences for shared decision making.

Regarding physician attitudes about screening, there were no significant differences among attending physicians, residents and interns regarding yearly PSA tests being the standard of care for asymptomatic men over age 50 (X^2 (98)=3.65, p> .20) or that providers face malpractice liability (X^2 (98)=5.64, p > .20). Interns differed marginally from residents and attending physicians (X^2 (97)=9.20, p=.06) concerning the sensitivity and specificity of the PSA as a screening test. Physicians differed significantly in correctly answering the statement, "It has not yet been demonstrated that detecting PCa earlier helps to save lives" (X^2 (98)=11.37, p=.02). All attending physicians correctly answered true to this statement while more residents (83.7%) versus interns (61.5%) responded correctly. Site (GU) and level of experience (attending physicians) were associated with annual screening for both African American men and all other groups of men. Despite the fact that it is based on a small sample, based on a review of the literature, this study of

primary care physicians is the first to examine the relationship between level of physician experience and PCa screening attitudes and practices.

At the conclusion of the patient-based intervention study, we will reassess the primary care physicians using the same questionnaire. Since the two assessments will be completed several years apart, the information will only provide a snapshot of the two clinics, as the staff will likely change significantly during that time. We will also assess if physicians were aware of our study, with respect to whether patients discussed the intervention materials with them.

Additional accomplishments during this grant year: 1*)* Finalized the procedures for patient accrual with our Department of Medicine collaborators (Drs. Fishman and Cole) and the randomized trial is underway. 2*)* Finalized the questionnaires to be included at the baseline and one-month assessments. 3) Developed a subject tracking system using an Access database. *We have a very detailed tracking system which will allow us to account for each subject we attempt to accrue to the study.* 4) We have developed an Access database for data entry of the interviews. *5)* An abstract has been accepted for presentation at the annual meeting of the Society of Behavioral Medicine:
Davis, K., Haisfield, L., Dorfman, C., Parker, E., Red, S., Dawson, D., Jackson, T., Goldman, P., Fishman, M., Cole, C., Taylor, K. Physicians' Attitudes and Practices Regarding Prostate Cancer Screening. To be presented at Society of Behavioral Medicine's 29th Annual Meeting and Scientific Sessions, San Diego, CA, March 2008.

Below we have inserted Tasks 1-3 from the Statement of Work and indicated progress made on each item.

*Task 1***.** Develop the educational website –COMPLETED

Task 2. Conduct participant accrual -- ONGOING

a. Eligible participants will be accessioned and the baseline interview will be administered by telephone. *This task is underway; we have accrued 65 men to the protocol.*
b. Participants will be randomly assigned to arm and the intervention materials distributed.--*Underway*
c. Data entry and quality control measures will be ongoing. *Underway.*
d. The medical record abstract form will be finalized and the research assistant trained to obtain screening information from patient charts. *Not yet begun.*
e. Begin accessing patient information from the charts. *Not yet begun.*

*Task 3***.** Conduct follow-up assessments: ONGOING

a. The Time 1 assessment will be conducted and the interventions will be distributed to participants. *Underway.*
b. The Time 2 interviews will be conducted at 1 month post intervention. *Underway.*
c. The Time 3 interviews will be conducted at 12 months post intervention. *Not yet begun.*

Key Research Accomplishments

1) Redesign and completion of the booklet.

2) Completion of the website.

3) Completion of the subject tracking database

4) Completion of a feasibility study.

5) Completion of a study of physician attitudes, knowledge and practices regarding prostate cancer screening.

6) Randomized trial is underway.

7) An abstract has been accepted for presentation at the annual meeting of the Society of Behavioral Medicine:
Davis, K., Haisfield, L., Dorfman, C., Parker, E., Red, S., Dawson, D., Jackson, T., Goldman, P., Fishman, M., Cole, C., Taylor, K. Physicians' Attitudes and Practices Regarding Prostate Cancer Screening. To be presented at Society of Behavioral Medicine's 29th Annual Meeting and Scientific Sessions, San Diego, CA, March 2008.

Reportable Outcomes – (see Appendix)

1) Revised Print Booklet

2) Website: The address of the website is www.prostatedecision.org and the Username is Guest and the Password is Guest1235.

Conclusions –

We do not yet have findings that are relevant for the scientific field. However, our work to date is extremely important for the progress of the proposed study. The revised print booklet has many strengths that the previous version did not have, while maintaining its original strong points. It is better organized and easier to read, while maintaining a level of detail for those men who wish to delve deeper into the topic. The feasibility study we conducted last year demonstrated men's computer/Internet access, their willingness to participate in an Internet-based study, and our access to the primary care clinics where we propose to accrue participants. It also increased our awareness of the potential for difficulties that some men face when attempting to gain up-to-date health-related information from the Internet. This information has been extremely important in helping to guide the development of the website. At present, we are preparing two manuscripts: one describing the physician study (see above), and a second which describes the development process of both the booklet and the website.

Plans

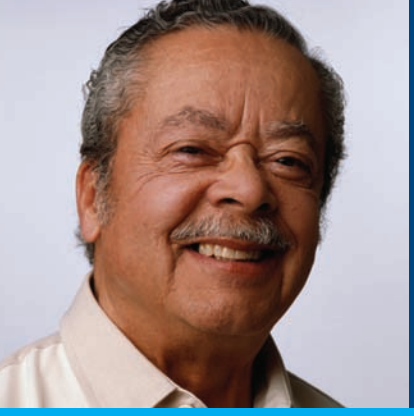
1) Continue accruing participants, working to improve participation rates and the rate of accrual. To accomplish this, we plan to hire another full-time research assistant and a half-time research assistant. During the development stages, we did not need these additional research assistants, but now that accrual is moving along, we will be able to fully use them to conduct subject accrual and telephone interviews. 2) Work to obtain better contact information through on line resources such as AutoTrack. Approximately 15-20% of the addresses and phone numbers that we receive from the two primary care practices are incorrect. We are presently seeking IRB approval to use this service. 3) Submit the two manuscripts described above, and 4) Finalize the questionnaires to be included in the one-year interview.

References

1. Jemal A, Murray T, Ward E, et al. (2005). Cancer Statistics, 2005. CA Cancer J Clin. 55(1):10-30.
2. Ries LAG, Eisner MP, Kosary CL, et al. (Eds.). SEER Cancer Statistics Review, 1975-2001, National Cancer Institute. Bethesda, MD. Available at: http://seer.cancer.gov/csr/1975_2001. Accessed Dec. 2004.
3. Prorok PC, Andriole GL, Bresalier RS, et al. (2000). Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. Control Clin Trials 21(6 Suppl):273S-309S.
4. Breen N, Wagener DK, Brown ML, et al. (2001). Progress in cancer screening over a decade: results of cancer screening from the 1987, 1992, and 1998 National Health Interview Surveys. J Natl Cancer Inst. 93:1704-13.
5. Ross LE, Coates RJ, Breen N, et al. (2004). Prostate-specific antigen test use reported in the 2000 National Health Interview Survey. Prev Med. 38(6):732-44.
6. Finney Rutten LJ, Meissner HI, Breen N, Vernon SW, Rimer BK. (2005). Factors associated with men's use of prostate-specific antigen screening: evidence from Health Information National Trends Survey. Prev Med. 40(4):461-8.
7. Mercer SL, Goel V, Levy IG, et al.(1997). Prostate cancer screening in the midst of controversy: Canadian men's knowledge, beliefs, utilization, and future intentions. Canadian J Public Health. 88(5):327-332.
8. O'Dell KJ, Volk RJ, Cass AR, Spann AL. (1999). Screening for prostate cancer with the prostate-specific antigen test: are patients making informed decisions?J Fam Pract 48(9):682-8.
9. Taylor KL, Shelby R, Kerner J, et al. (2002). Impact of undergoing prostate carcinoma screening on prostate carcinoma-related knowledge and distress. Cancer. 95(5):1037-44.
10. Laara E, Day NE, Hakama M. (1987). Trends in mortality from cervical cancer in the Nordic countries: association with organised screening programmes. Lancet. 1(8544):1247-1249.
11. Collins MM, Barry JJ. (1996). Controversies in prostate cancer screening: Analogies to the early lung cancer screening debate. JAMA, 276(24):1976-1979.
12. Brawley OW, Kramer BS. (2005). Cancer screening in theory and in practice. J Clin Oncol. 23:293-300.

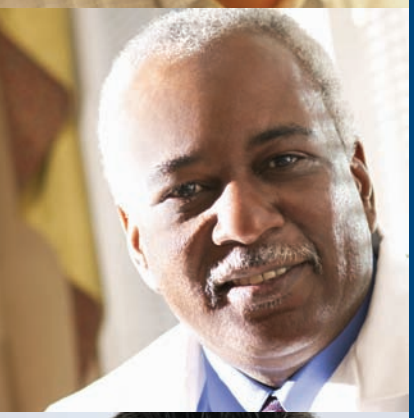
13. Ornstein DK, Rayford W, Fusaro VA, et al. (2004). Serum proteomic profiling can discriminate prostate cancer from benign prostates in men with total prostate specific antigen levels between 2.5 and 15.0 ng/ml. J Urol. 172(4 Pt 1):1302-5.
14. Watson RW, Schalken JA. (2004). Future opportunities for the diagnosis and treatment of prostate cancer. Prostate Cancer Prostatic Dis. 7 Suppl 1:S8-S13.
15. Mahadevia PJ, Fleisher LA, Frick KD, et al. (2003). Lung cancer screening with helical computed tomography in older adult smokers: a decision and cost-effectiveness analysis. JAMA. 289(3):313-22.
16. Chapman GB, Sonnenberg FA. (2000). Introduction. In: GB Chapman and FA Sonnenberg (eds.), Decision Making in Health Care. Theory, Psychology, and Applications (pp. 3-19). New York: Cambridge University Press.
17. Kaplan RM, Frosch DL. (2005). Decision making in medicine and health care. Annu Rev Clin Psychol. 1:19.1-19.32.

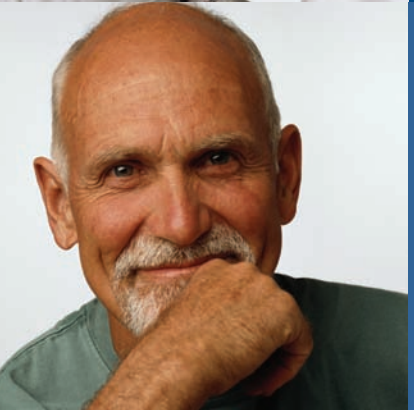
Appendix
Revised Print Booklet



PROSTATE CANCER SCREENING

Making the Best Choice





Lombardi Comprehensive Cancer Center

Georgetown University Medical Center

Georgetown University Hospital

Washington Hospital Center

Making the Best Choice

Getting tested for prostate cancer is something that many men do each year. On the other hand, there are some men who have decided not to get screened, and others who have not yet made a decision either way. Regardless of which group you are in, you may be wondering why you should spend time reading this booklet about prostate cancer screening.

You may be surprised to know that there is uncertainty about whether men should get screened for prostate cancer.

Based on current medical knowledge, we know that screening can find prostate cancer in its early stages. But, we don't yet know whether finding prostate cancer early will *save lives*. The research needed to fully answer this question will not be completed for several years.

What we do know is that all men should understand the pros and cons of prostate cancer screening to make an informed decision for themselves. Whether to be screened for prostate cancer is an individual choice. Your decision should be based on the facts that you learn, discussions with your doctor, and your own beliefs. After going through this process, some men prefer to be screened, some men prefer to not be screened, and some men remain unsure. After reading the information in this booklet and having a discussion with your doctor, you will be able to make the best choice for yourself.

This booklet will help you to understand what is known and what is not known about prostate cancer screening.

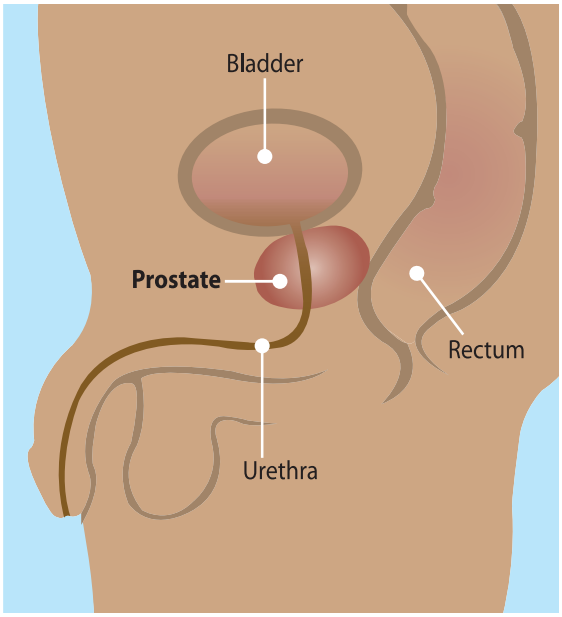
In addition, we provide a worksheet, on pages 22–23, to help you consider your own priorities and beliefs about prostate cancer screening.

Reading this booklet will help you to do many things.

Facts about the prostate gland and prostate cancer

What is the prostate?

The **prostate** is a **gland** in men that makes the fluid that carries sperm. It is located in front of the **rectum** and just below the **bladder**. It's about the size of a walnut.



What kind of prostate problems can a man have?

- **Benign Prostatic Hyperplasia (BPH)**
  BPH is enlargement of the prostate. BPH is not **cancer**. The prostate tends to increase in size as men get older. This can cause the **urethra** to narrow and decrease urine flow.

- **Prostatitis**
  Prostatitis is an inflamed prostate, usually due to an infection. Prostatitis is not cancer.

- **Prostate Cancer**
  Prostate cancer occurs when prostate cells do not grow normally. The cells divide and create new cells that the body does not need. These cells form a mass of tissue called a **tumor** and can spread elsewhere in the body.

What is prostate cancer screening?

Before going into the details of prostate cancer screening (page 5), we want to give you some basic information to get started. **Screening** means looking for early signs of disease in people who have no **symptoms**. The main screening tests for prostate cancer are the:

- **Digital rectal examination (DRE)**
- **Prostate specific antigen (PSA) blood test**

The DRE and PSA tests cannot tell if you have cancer; they can only let you know if you need to have further tests.

Screening Recommendations

All medical organizations recommend that doctors and patients:

- Discuss how screening may help and how screening may cause problems
- Share the decision about whether a man should be screened

The American Cancer Society, the American College of Physicians, the American Medical Association, and the American Urologic Association recommend offering screening every year:

- Beginning at age 50 for the general population
- Beginning at age 45 for African-American men, and men who have a father or brother with prostate cancer
- To men who are likely to live at least 10 years

These organizations recognize the uncertainty of whether screening helps men. They recommend that men make a decision about screening only after they understand the risks and the benefits of the tests.

On the other hand, the United States Preventive Services Task Force (USPSTF), the leading group of experts in screening and prevention, states that there is *not enough evidence* to make a recommendation either for or against screening. The USPSTF agrees with the other organizations that doctors and patients should make a **shared decision** about whether to get screened.

The fact that organizations differ in their conclusions about screening suggests that we don't yet have all of the answers about prostate cancer screening. This may make it hard for men who are trying to make a decision about screening.

Since there is no right or wrong answer about whether to get screened, this booklet is meant to help you make the best decision for yourself.

Will getting screened for prostate cancer help you?

Based on current medical knowledge, there is no way to be certain whether prostate cancer screening will help you. This may seem confusing, because **we have been taught to find problems early and then to treat them.** Most people believe that all cancers will lead to pain and death, unless they are found early and are treated right away. **This is true in some, but not all, cases of cancer.**

What is surprising to many people is that **most prostate cancers do not cause health problems and death.** This may be hard to believe, but here are some facts you should be aware of:

Most prostate tumors NEVER become a very serious health problem.

- These tumors grow slowly.
- They usually don't cause any **symptoms** during the man's life and the man dies of something else.

Autopsies on men who have died from causes other than prostate cancer have shown that up to 60% of men over the age of 60 had prostate cancer and did not know it. For these men, prostate cancer had never become bothersome enough to be diagnosed.

Some prostate tumors DO become a very serious health problem.

- These tumors can grow quickly and can spread beyond the prostate.
- They can cause illness and death.

Almost 30,000 men die each year from prostate cancer in the U.S. Prostate cancer is the second leading cause of cancer-related deaths among men. Prostate cancer can be a very serious and fatal disease.

Unfortunately, doctors do not yet know how to figure out which prostate cancers will spread and which will not. If we could accurately predict which cancers will grow, then we could treat only these patients. This issue is at the heart of understanding how prostate cancer screening can help and how it can cause problems. Men need to understand both the pros and cons of prostate cancer screening to make an **informed decision** about what is best for them. The pros and cons of screening are described on the following pages.

Learn the Facts About Prostate Cancer Screening

Steps involved in screening

Screening for prostate cancer can involve a number of steps. What happens in the first step affects what happens in the next steps.

This booklet is meant to help you make the best decision for yourself. To help you decide, let's begin with the basics about screening.

FIRST STEP What to expect if you get screened

1. The DRE: A Doctor's Exam

- **DRE** stands for **D**igital (finger) **R**ectal **E**xamination.
- It is a quick exam to check the prostate for hard or lumpy areas.
- For this test, a doctor inserts a gloved and lubricated finger into the rectum.
  - This allows the doctor to feel the back portion of the prostate.
  - Your doctor will feel its size and any irregular or abnormally firm areas.
- The DRE is a brief procedure which can cause some discomfort.

2. The PSA: A Blood Test

- **PSA** stands for **P**rostate **S**pecific **A**ntigen.
- PSA is a substance made by the prostate gland. The prostate gland releases it into the blood.
- The PSA test measures the level of PSA in the blood.
- As a rule, the higher the PSA level in the blood, the more likely it is that a prostate problem is present.
- However, many factors, such as older age, **BPH**, and African American race, can increase PSA levels even when prostate cancer is not present. Further, some prostate glands produce more PSA than others, meaning that some men will have higher PSA levels but will not have prostate cancer.

NEXT STEP Discussing the Results with Your Doctor

Because many factors can affect PSA levels, your doctor is the best person to interpret your PSA test results. Here are some commonly asked questions:

1. What is the normal range for a PSA test?

Most men have PSA levels under 4. A PSA level under 4 is considered a normal PSA level by most doctors. However, some research has suggested that what is considered normal should be lower than 4. To decide if follow-up testing is necessary, some doctors use different PSA values that depend on a man's age and race (see page 26 for more information).

2. How accurate are screening tests?

No test is right all the time. The same is true of the PSA test and DRE. The PSA test is better at finding small cancers, or cancers that cannot be felt by the DRE. The DRE can sometimes help find cancers in men with normal PSA levels. Both tests are often performed, although some men and some doctors choose to use only the PSA test.

False Positive Results

- This happens when your results are abnormal, but you really DO NOT have cancer.
- In other words, the screening results can suggest that you have a cancer that is not really there.
- This can cause you to worry and have further tests that turn out to have been unnecessary.

False Negative Results

- This happens when your results are normal, but you really DO have cancer.
- So, the screening tests can also miss finding a cancer that is really there.
- This can cause you to fail to have further tests that you may need.

3. What if the first set of screening results is *abnormal*?

This could mean one of many things:

- The results may be wrong and further testing will show a normal result.
- The abnormal PSA results may be due to a non-cancerous condition, such as **benign prostatic hyperplasia** (BPH), **prostatitis**, or recent medical procedures you may have had (such as **cystoscopy** or **catheterization**).
- You may have prostate cancer. **However, most men without symptoms (approximately 75%) who have an abnormal screening result DO NOT have cancer.**

How accurate is the PSA test?

Consider a group of

100

men who are

- in their 60s
- at **average risk**
- have not been screened before

are tested for prostate cancer.

87
men
have a normal PSA.

The results were
NEGATIVE
(less than 4.0)
and no further tests
are done.

13
men
have an abnormal PSA.

The results were
POSITIVE
(more than 4.0)
and further testing
is done.

2
men
DO have cancer.

The test was not accurate.

FALSE NEGATIVE

85
men
DON'T have cancer.

The test was accurate.

TRUE NEGATIVE

10
men
DON'T have cancer.

The test was not accurate.

FALSE POSITIVE

3
men
DO have cancer.

The test was accurate.

TRUE POSITIVE

FINAL STEPS If the Test Results Are Abnormal

This next section describes what will happen if you have an abnormal prostate cancer screening result. This will help you know a little more about follow-up testing before you make a screening decision.

1. A Repeat PSA Blood Test

- If your PSA test or DRE was abnormal, your doctor may suggest a repeat PSA test. He or she may also test for the level of 'free' PSA (see page 25).
- This will help to see if the earlier test was accurate. In addition, a repeat PSA test can determine whether the PSA level changes over time. Doctors refer to this as the PSA velocity (see page 25 for more details).
- If it is still high, your doctor may refer you to a **urologist**. This is a doctor who has special training in problems related to the prostate.

2. An Ultrasound Test

- The urologist may perform a **T**rans**R**ectal **U**ltra**S**ound **(TRUS).**
- A small lubricated probe is inserted into the rectum.
- The probe has sound waves that bounce off the prostate. This produces a picture that the doctor can see on a video screen.

3. A Biopsy During the Ultrasound

- If the urologist suspects cancer, tiny samples of the prostate may be removed with a needle during the TRUS procedure. This is called a **biopsy**.
- The biopsy is usually performed in the urologist's office.
- The samples are later looked at under a microscope to find out if cancer cells are present.

4. A Discussion with Your Doctor About Your Biopsy Results

- If the biopsy results are normal: You probably do not have cancer. Just like the PSA and DRE, biopsies are not 100% accurate, but they are the best method we have for finding out if cancer is present. Together with your doctor, you will decide whether to continue prostate cancer testing, and if so, how often you will be tested.
- If the biopsy results are abnormal: You may have cancer. No two men with prostate cancer are the same, however. When prostate cancer is found at an early stage and has not spread beyond the prostate, the doctor and patient have a choice to make. They need to choose between one or more **active treatments** and **watchful waiting** (see page 13–14).
- Many factors affect the decision whether to treat the disease, and also how to treat the disease. These are described on pages 14–16.

Is screening right for you?

The choice is yours.

Below are two examples of what men have said about prostate cancer screening. It is important to know that although they feel differently about their screening decisions, both men's feelings are reasonable. Their feelings reflect the different experiences that can result from getting screened. There is no right choice about screening, because there is no evidence that either choice will lead to a better health outcome.

Some men who *believe that* getting screened was helpful have said the following:

I've always believed it's better to know more rather than less about my health. That's why I signed up for a free prostate screening program. It showed that my PSA level was higher than normal, so the doctor recommended a biopsy. The biopsy results showed that I didn't have cancer. I knew then that getting screened was the best decision for me. Getting screened gave me peace of mind to know that I do not have cancer.

Some men who *question whether* getting screened was helpful have said the following:

When I turned 50, I got my PSA checked, because that's what the ads say and my wife insisted. It came back high and my doctor rechecked it and it was still high, so I got a biopsy. The biopsy said I didn't have cancer, which made me feel good at first. But my PSA kept going up. Now I'm 55. I've had three biopsies over the past 5 years—all normal. My PSA isn't going up anymore and the doctor says this all happened just because my prostate is enlarged. But I still worry sometimes that I might have cancer. I often wonder whether this PSA test has helped me at all.

Facts You Should Know If Prostate Cancer Is Found

When prostate cancer is found, it may not always lead to active treatment.

One of the major problems with prostate cancer screening is that, once the cancer is found, there is no foolproof way of knowing what the cancer will do next.

- Will it grow quickly and spread or will it grow slowly and stay where it is?
- Will it cause symptoms?
- Could it cause death?

Here are the facts:

- The **Gleason Score** is one way to measure how fast-growing a cancer could be. However, its predictions are not always accurate.
- Doctors also look at other ways to predict how fast prostate cancer may be growing, such as **prostate intraepithelial neoplasia** (PIN).
- Because we can't accurately identify which prostate cancers will grow quickly, it is impossible to know for certain who will benefit from treatment and who will not.
- Due to this uncertainty, most men in the U.S. choose an active treatment.
- As a result, some prostate cancers are treated unnecessarily, meaning that the treatment does not help a man live a longer or healthier life.
- This problem, called **overtreatment**, is thought to be a particular problem with prostate cancer because prostate cancer often grows slowly. Overtreatment is a problem even for African American men, who are at higher risk for prostate cancer.

As a result of this uncertainty, men and their doctors must decide:

WHETHER TO: Risk engaging in watchful waiting when a cancer could become fatal	OR	WHETHER TO: Risk treating a cancer that may never cause any problems
The problem with NOT TREATING prostate cancer that may be FAST-GROWING: ■ The cancer may spread, making it more difficult to treat the cancer successfully. ■ Treatment options may be limited once the cancer has spread.		**The problem with TREATING prostate cancer that may be SLOW-GROWING:** ■ The side effects of active treatment could make a man's life more difficult than the cancer ever would have. ■ So, the side effects of treatment may be a high price to pay for treating a slow-growing prostate cancer.

For men with early stage prostate cancer, there are 2 main decisions to make.

1. WHETHER to actively treat the disease

- Some men decide to have **active treatment** for their prostate cancer.
- Some men choose *not* to have active treatment. The doctor and patient make a **shared decision** to watch the prostate cancer closely by performing the PSA test, DRE, and other diagnostic tests on a regular basis. Then, the cancer is treated only if and when it shows signs of growing or of causing symptoms.

2. HOW to actively treat the disease

If a man decides to treat his prostate cancer, there are a number of treatment options. Active treatments include:

- **Surgery (radical prostatectomy):** Surgery is performed to remove the prostate.
- **External radiation therapy:** Radiation is directed at the prostate. This helps to destroy cancer cells.
- **Internal radiation therapy (brachytherapy):** Surgery is performed to place small radioactive pellets inside or near the cancer. These help to destroy cancer cells.
- **Hormone therapy:** Certain hormones are given or removed. This helps to keep cancer cells from growing.
- **Cryotherapy:** A special probe is placed inside or near the prostate cancer. This helps to freeze and destroy the cancer cells.

Are some treatments better at saving lives than others?

It's hard to believe, but at this time we don't know which of the standard treatments is the most effective at reducing deaths due to prostate cancer.

When making treatment decisions, there are several factors to consider.

Many factors affect the treatment decisions men make.

- A man's age
- The stage of the cancer
- A man's other medical conditions and overall health
- A man's feelings about treatment side effects and what impact they may have on his life
- What a man feels is best for him and his priorities
- How a man feels about the scientific uncertainty of the effectiveness of treatments
- How a man weighs his length of life versus his quality of life

Do these active treatments have side effects?

- **Side effects from prostate cancer treatment depend mainly on 3 things:**
  - The type of treatment
  - A man's age
  - A man's overall health
- **Men who are treated for early-stage prostate cancer may have the following side effects:**
  - Pain
  - Discomfort
  - **Impotence** (being unable to have and keep an erection)
  - **Incontinence** (being unable to hold urine and feces)
- **Side effects can vary.**
  - They can be mild to severe.
  - They can be temporary, or they may be permanent.
  - Some can be more easily treated than others.
- **Your doctor will be able to help.**
  - When a doctor explains the treatment choices, he or she can discuss the side effects with you and let you know what to expect.
  - Also, a doctor may be able to perform surgery or prescribe medicine to relieve some side effects, including impotence.
  - Together, you and your doctor will consider many factors in deciding what treatment is best for you.

How long do the side effects of treatment last?

It is hard to say.

- Studies have been done to answer that question. But, we still can't say for sure how many men will experience side effects, or how long they will last.
- We just know that men who are treated for prostate cancer are likely to experience side effects. See page 29 for more information on side effects.

Besides treatment, can anything else cause these same side effects?

Yes:

- **A cancer that is growing:** These problems can be caused by the prostate cancer itself.
- **Men without prostate cancer** can develop these same symptoms due to:
  - Getting older
  - Other illnesses

Current treatment options for late stage prostate cancer

Most prostate cancers that are diagnosed after screening will be caught at an early stage. More advanced prostate cancers that have spread beyond the prostate can be difficult to treat. In addition, often there is no cure and no way to keep **late stage** cancers from spreading further. Men with advanced prostate cancer should discuss the best course of action with their doctors.

Steps You Can Take To Make The Best Choice

1 KNOW the risk factors for prostate cancer: Think about *your* risks.

What increases your chances of having prostate cancer?

Based on studies, here's what we know, so far.

Your Age

- The chance of having prostate cancer increases with age, particularly after age 50.
- More than 70% of all prostate cancers are diagnosed in men over 65.

Your Family History

- Men with a father or brother who has had prostate cancer are at greater risk for developing it themselves.
- The younger a man is when he has prostate cancer, the greater the risk for his male family members.

Your Race

- Prostate cancer is more common in African-American men than in white men. The death rate from prostate cancer is also higher for African American men (see page 28).
- It is less common in Hispanic, Asian, Pacific Islander, and Native American men than in white men. But they do get it.
- Medical experts do not understand the causes of these differences.

Age, family history, and race are all things that you have no control over. But knowing this can help you to decide how to best take care of yourself.

Diet. Scientists are trying to learn more about how diet may make a difference in men's risk for prostate cancer.

- Some studies suggest that a diet high in fat, including fried or creamy foods, may increase the risk of prostate cancer. But not all experts agree.
- Researchers are studying several factors that may lower a man's chance of developing the disease, such as:
  - a diet high in fruits, vegetables (tomatoes, in particular), and soy
  - the use of nutritional supplements (e.g., selenium, vitamin E).

2 LEARN the symptoms of prostate cancer.

There *may be no* symptoms.

Most men who are diagnosed with prostate cancer have NO symptoms.

- So, you can have prostate cancer and not notice any problems.
- This is the potential benefit of undergoing screening: that the screening tests can detect cancer before there are symptoms.

Sometimes, there *are* symptoms.

Some symptoms might be a sign of prostate cancer. This is particularly true when the cancer is more advanced. Symptoms can include:

- The need to urinate frequently, especially at night
- Weak or interrupted urine flow
- Pain or burning feeling while urinating
- The inability to urinate
- Blood in the urine
- Constant pain in the lower back, pelvis, or upper thighs
- Fatigue (extreme tiredness)
- Weight loss (when a man is not trying to lose weight)

Often, symptoms *are not* due to cancer.

- They can be caused by other prostate problems that are not cancer.
- They can be caused by other medical conditions.
- They can also be caused by certain medications.
- Some symptoms (e.g., fatigue) can be caused by aging.

What to do *if you do have* symptoms:

- If you have any of these symptoms, see your doctor.
- Get a diagnosis. Find out what is causing your symptoms.

3 TALK with your doctor about screening: Ask questions.

Talk with your doctor.

After you read the information in this booklet and consider your own priorities and beliefs, talk with your doctor. Talking with your doctor to make a **shared decision** is an important step in making health decisions.

Consider asking these questions.

To decide whether screening is right for you, discuss screening with your doctor and the people important in your life. We have listed some questions you might want to discuss with your doctor.

1. Can you explain why I should consider getting screened for prostate cancer?
2. Can you also explain why I should consider not getting screened?
3. If I am screened and then diagnosed with prostate cancer, what are some of the treatments I might want to consider?
4. I have learned that doctors disagree about whether men who do NOT have symptoms should be screened for prostate cancer.
   - Can you tell me your views about this?
   - Can you also tell me what you would recommend in my particular case?

Plan to ask questions of your own.

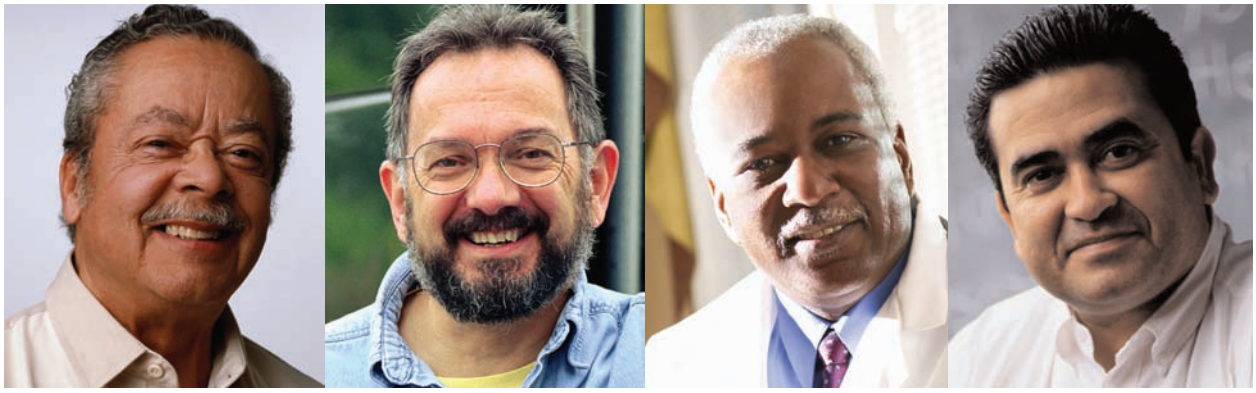
We have left space for you to write in your own questions.

Decide How You Feel And What Is Important to You

Below are issues to think about when making a decision about screening.

First, read the following sentences and check Yes or No for each one, depending on whether the sentence sounds like you or not. Then, look at all the sentences that you checked yes. See whether you lean more toward getting screened, or more toward not getting screened.

Men who have made these statements often decide to get screened.	Does this sound like you?	
	YES	**NO**
Getting screened will give me peace of mind about prostate cancer.		
Even though prostate cancer may never cause me any problems, I prefer to get screened so that I know whether I have prostate cancer.		
Getting screened will help me feel like I am doing everything I can do for my health.		
I understand that screening has not yet been proven to save lives. Even so, I prefer to get screened because I think it is better to be 'safe than sorry.'		
If I am screened and then diagnosed with prostate cancer, I will need to either accept living with untreated cancer or accept the side effects of treatment. Even so, I prefer to get screened because these potential consequences are worth the *possibility* of a longer life.		



Men who have made these statements often decide NOT to get screened.	Does this sound like you?	
	YES	**NO**
Since prostate cancer may never cause me any problems, I think I am better off *not* getting screened.		
Future research may demonstrate that getting screened helps men live longer. But, because we do not yet know for certain whether prostate cancer screening saves lives, I prefer to not get screened at this time.		
Screening may give an abnormal result when cancer is not present. It may also give a normal result when cancer is present. Therefore, I will wait until the screening test is more accurate before I get tested.		
Screening can cause a false positive result that leads to an unnecessary prostate biopsy. Therefore, I prefer to not get tested until the screening test is more accurate.		
If I am screened and then diagnosed with prostate cancer, I will need to either accept living with untreated cancer OR accept the side effects of treatment. These potential consequences would not be worth the *possibility* of a longer life. Therefore, I prefer to not be screened at this time.		

Adapted from Gattellari, M. & Ward, J.E. (2003).

Making the best choice: Putting it all together

When you make a decision about whether to undergo prostate cancer screening, it is important to understand the possible benefits and risks of screening. Understanding what is most important to you is also essential for making the best choice. Use the decision aid on the previous two pages to help you understand the issues that are most important to you.

In addition, it's important to keep in mind that:

- Although the information in this booklet will help you, it cannot replace the conversations you have with your doctor, friends, family, and men who are facing the same screening decision.
- There is not a right or wrong choice about prostate cancer screening, based on current medical information.
- The best choice for you can be made only after you have all of the relevant information.

The following pages in this booklet contain:

- Statistics and Research Issues
- Glossary
- References for selected research articles
- Resources for further information

Please continue reading to learn additional information about screening.

Statistics and Research Issues

When will more be known about prostate cancer screening?

Researchers at the National Cancer Institute are working on a large study (**clinical trial**) to answer the main question about prostate cancer screening: Are men who get screened each year less likely to die of prostate cancer, compared to men who do not get screened? Results are expected in 5–10 years. For further information on this trial, and a similar European trial, see *National Organizations* (page 35).

What is the best method for measuring PSA?

Researchers are exploring several different ways of measuring PSA.

PSA velocity

- PSA velocity is based on how quickly PSA levels change over time.
- A sharp rise in the PSA level raises the suspicion of cancer.

PSA density

- PSA density considers the relationship between the PSA level and the size of the prostate.
- This means that an elevated PSA might not be worrisome if a man has a very enlarged prostate.
- This approach increases the risk that a cancer might be overlooked in a man with an enlarged prostate.
- Therefore, the use of PSA density to interpret PSA results has not been settled.

Free versus attached PSA

- PSA circulates in the blood in 2 forms: “free” or “attached” to a protein molecule.
- With **benign** prostate conditions, there is more free PSA. With prostate cancer, there is more of the attached form of PSA.
- Many doctors use this measure to help them interpret a man’s PSA level.

Age-adjusted PSA

- Age is an important factor in increasing PSA levels. For this reason, some doctors use age-adjusted PSA levels to determine when diagnostic tests are needed.
- When age-adjusted PSA levels are used, a different PSA level is defined as normal for different age groups.
- Doctors who use this method generally suggest that a normal test:
  - for men younger than age 50 is a PSA level below 2.4 ng/ml.
  - for men between 50–70 is a PSA level below 4.0 ng/ml.
  - for men in their 70's is a PSA level below 6.5 ng/ml.
- Doctors do not agree about the accuracy and usefulness of age-adjusted PSA levels.

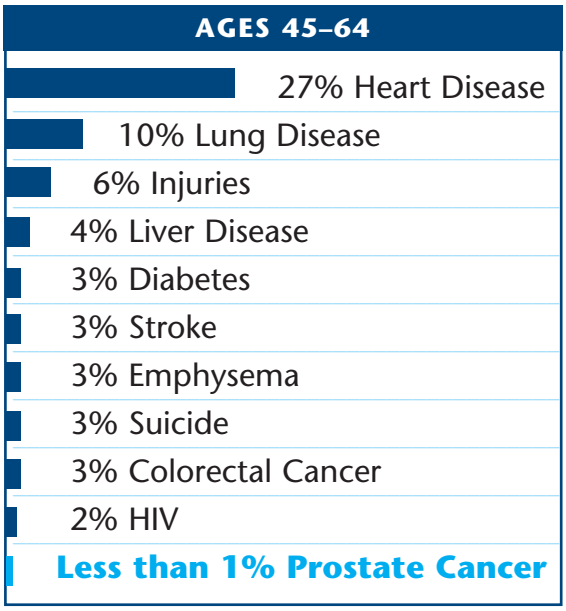
Race-Adjusted PSA

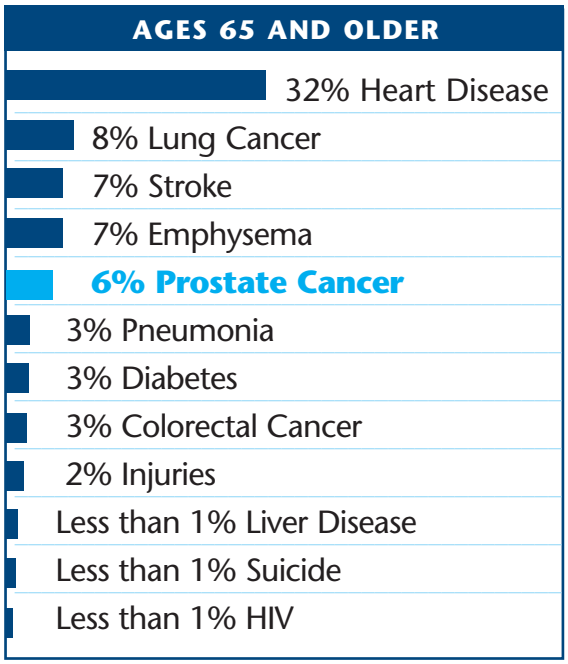
- Some studies have shown that African American men have higher PSA levels than white men who are of similar age and health.
- It has been suggested that race-adjusted PSA be used, similar to how some doctors use age-adjusted PSA.
- However, as with age-adjusted PSA levels, doctors do not agree whether it is useful to use different PSA levels for men with different racial backgrounds.

These different ways of measuring PSA may make prostate cancer detection more accurate. However, even if we can improve methods of finding prostate cancer, we still do not know whether finding it reduces the number of deaths from it.

What diseases are most likely to cause death in men?

Men have a greater chance of dying from diseases other than prostate cancer. The two figures below show the top twelve causes of death in younger and older men:





U.S. men who are 45-64 years of age: prostate cancer ranks 11th, behind all other common causes of death.

U.S. men who are 65 years of age and older: prostate cancer ranks 5th, behind heart disease, lung cancer, stroke, and emphysema.

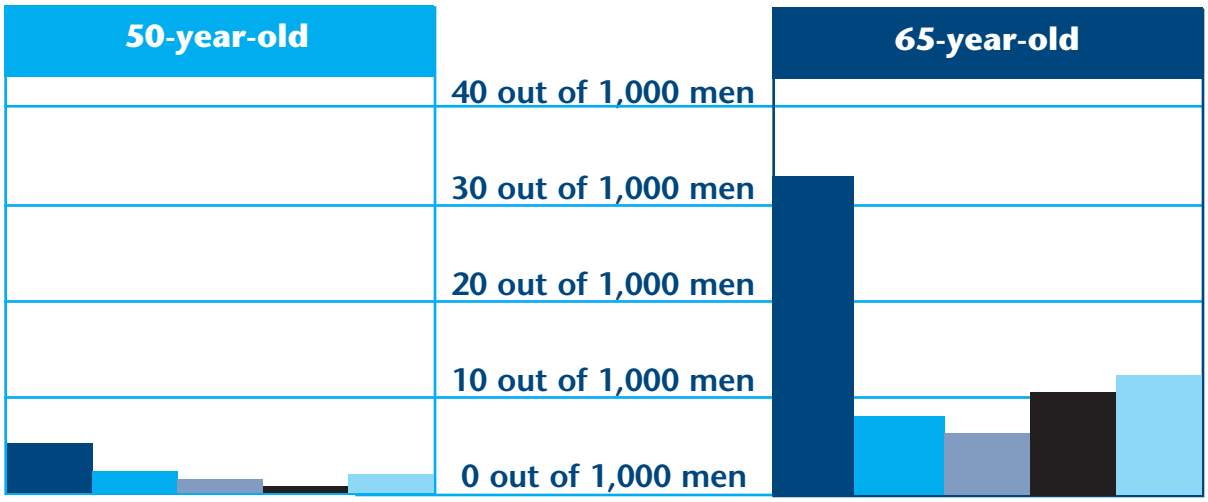
- These graphs show that many other diseases cause death more often than prostate cancer does. Even though prostate cancer is given a lot of attention in the media and by doctors, there are many other diseases that are more deadly than prostate cancer. Talk to your doctor about how to prevent them.

- As a result, most men with prostate cancer end up dying of illnesses other than prostate cancer. This is why experts sometimes say, "More men die *with* prostate cancer than *of* prostate cancer."

Centers for Disease Control and Prevention, National Canter for Health Statistics. Health Data for All Ages. http://www.cdc.gov/nchs/health_data_for_all_ages.htm. May 1, 2007

What are the chances of dying from prostate cancer?

- Out of 1,000 men, this chart shows the chance of dying from prostate cancer in the next 15 years—for 50-year-old men and for 65-year-old men.



For a 50-year-old man, his chance of dying from prostate cancer in the next 15 years is fairly low (5 or fewer in 1000 men).

- African-American
- American Indian and Alaskan Native
- Asian and Pacific Islander
- Hispanic
- White

For a 65-year-old man, the chance of dying from prostate cancer in the next 15 years rises. This is particularly true for African American men.

- Even though your chance of dying from prostate cancer increases with age, it remains relatively low overall. About 3% of all males will die of prostate cancer over their lifetime.

Fay, M.P., Pfeiffer, R., Cronin, K.A., Le, C. and Feuer, E.J. (2003). Age-conditional probablities of developing cancer. *Statistics in Medicine,* 22(11): 1837-1848.

Issues related to treatment and disease outcomes

Choosing active treatment is a particular concern for older men.

- Men over age 75 are more likely than younger men to have other life-threatening health concerns (heart disease and diabetes, among others).
- Because prostate cancer often grows slowly, these other illnesses are more likely than prostate cancer to cause death.
- As a result, older men are less likely to benefit from finding and treating prostate cancer.

More details on side effects of treatments

- The chart below shows the percentages of men who continue to experience certain common side effects up to 5 years after they have completed surgical or radiation treatment.
- The wide range of percentages represents the collection of results from different studies. Complication rates may be reduced as the available treatments improve over time.
- We can't say for sure how many men will experience these common side effects, or how long the side effects will last. The main point to understand is that many men do experience these side effects following treatment for prostate cancer.

	Surgery (general or nerve-sparing)	**Radiation therapy**
Problems with **urination**	15%–50%	2%–16%
Problems with **bowel movements**	3%–20%	6%–25%
Problem with **sexual function**	20%–79%	20%–64%

We show this information to give you an idea of the side effects men may face when they are treated for prostate cancer. However, in the event you are diagnosed with prostate cancer, you and your doctor would need to consider many factors in deciding what treatment is best for you.

Glossary

Active treatment: Surgery, external radiation therapy, internal radiation therapy, hormone therapy, cryotherapy, or a combination of these treatments. The term "active treatment" is often used to distinguish these treatments from watchful waiting.

Average-risk: Men who are at average risk are all men who are not African American and who do not have a father, brother, or son diagnosed with prostate cancer before age 65.

Benign: Not cancerous.

Benign prostatic hyperplasia (BPH): Enlargement (growth) of the prostate. BPH is not cancer, but it can cause some of the same symptoms, including starting and stopping the flow of urine.

Biopsy: The removal of a sample of tissue, which is then examined under a microscope to check for cancerous changes.

Bladder: The organ that stores urine.

Bowel movement problems: Can include frequent bowel movements, sudden urges to have bowel movements, or not being able to control your bowel movements.

Brachytherapy: Radioactive material sealed in needles, seeds, wires, or catheters is placed directly into or near the tumor. Also called internal radiation, implant radiation, or interstitial radiation therapy.

Cancer: A term for diseases in which abnormal cells begin to grow out of control. Cancer cells are able to invade nearby tissues and to spread through the bloodstream to other parts of the body.

Catheterization: A procedure whereby a thin tube (catheter) is inserted into the urethra to drain and empty the bladder.

Clinical Trial/Study or Research Study: A study involving people that is designed to answer medical questions and to find better ways to prevent or treat disease.

Cryotherapy: Treatment performed with an instrument that freezes and destroys abnormal tissues.

Cystoscopy: Examination of the bladder and urethra using a thin, lighted instrument (called a cystoscope) inserted into the urethra. Tissue samples can be removed and examined under a microscope to find out if disease is present.

Digital rectal examination (DRE): A procedure in which the doctor inserts a gloved, lubricated finger into the rectum to feel the rectum and prostate for anything abnormal. Some tumors of the prostate can be felt during this exam.

Early-stage prostate cancer: Cancer that is confined to the prostate and has not spread to other parts of the body.

European Randomized Screening for Prostate Cancer (ERSPC): A major European study that should tell us whether screening for prostate cancer should be a part of routine health care or not. The study is connected with another big study in the U.S. called the **Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial** and involves 8 countries.

External radiation therapy: Radiation therapy that uses a machine to aim high-energy rays at the cancer. Also called external beam radiation.

False negative screening result: When a screening test shows a normal test result, but cancer is actually present.

False positive screening result: When a screening test shows an abnormal test result, but cancer is actually absent. A prostate biopsy that is normal (not cancerous) means that an abnormal screening test was incorrect (i.e., falsely positive).

Family history: Prostate cancer seems to run in some families. Having a father or brother (first degree relatives) with prostate cancer doubles a man's risk of developing this disease. The risk is higher for men who have had several first-degree relatives with the disease or if their relatives were young when the cancer was found.

First degree relative: A relative in your immediate family: For prostate cancer this means father, a brother, or a son. Cousins, uncles, grandparents are 'second degree' relatives.

Gland: An organ that produces and releases one or more substances used by various parts of the body.

Gleason Score: A system of grading prostate cancer tissue based on how it looks under a microscope. Gleason scores range from 2 to 10 and indicate how likely it is that a tumor will spread. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread; a high Gleason score means the cancer tissue is abnormal and the tumor is more likely to spread. The Gleason score can be used as a guide to understanding how fast growing a tumor might be, but it is not an exact prediction.

Hormone therapy: Treatment of cancer by removing, blocking, or adding hormones.

Impotence: Not being able to have an erection that is adequate for sexual intercourse.

Incontinence: Not being able to hold or control the flow of urine or feces.

Informed decision: A decision that is made after all of the relevant information and possible outcomes have been examined.

Internal radiation therapy: Radiation therapy that is given internally (inside the body). This is done by placing radioactive material that is sealed in needles, seeds, wires, or catheters directly into or near the tumor. Also called implant radiation, interstitial radiation, or brachytherapy.

Late stage cancer: Cancer has spread beyond the outer layer of the prostate to nearby tissues (called Stage C or Stage III), or it has metastasized (spread) to the lymph nodes or other parts of the body, such as the bladder, rectum, bones, liver, or lungs (called Stage D or Stage IV).

Overdiagnosis (overtreatment): Finding and treating cancer that would otherwise not have been noticed in the patient's lifetime. Such cancers, known as latent tumors, grow slowly or not at all.

Prostate cancer: A disease in which prostate cells grow out of control. Spurred by changes in the genes, the glandular cells of the prostate multiply abnormally.

Prostate gland: A male sex gland. The prostate produces fluid that forms part of semen that carries sperm.

Prostatic intraepithelial neoplasia (PIN): PIN is the noncancerous growth of cells of the prostate gland. Having high-grade PIN may increase the risk of developing prostate cancer.

Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial: A large-scale National Cancer Institute sponsored study to determine if screening tests will reduce the number of deaths from prostate, lung, colorectal, and ovarian cancers.

Prostate specific antigen (PSA): A protein produced by cells of the prostate gland. PSA circulates in the bloodstream and can be measured with a simple blood test. PSA levels rise in the blood of some men who have prostate enlargement, inflammation (swelling), infection, or cancer.

Prostatectomy: An operation to remove part or all of the prostate. Radical (or total) prostatectomy is the removal of the entire prostate and some of the tissue around it.

Prostatitis: Inflammation of the prostate. Prostatitis is not cancer.

Rectum: The lower part (last 8 to 10 inches) of the large intestine. The rectum stores solid waste until it leaves the body through the anus.

Risk factor: Something that increases a person's chance of developing a disease.

Screening: Checking for signs of disease in a person who has no symptoms. For example, screening measures for prostate cancer include digital rectal examination (DRE) and the PSA blood test. Screening may refer to programs that are designed to test many people.

Sexual functioning problems: Can include not being able to get an erection, not being able to have intercourse, or being unhappy with the erections you can get.

Shared Decision-Making: The process of a patient working together with his health care providers to make decisions about screening and/or treatment.

Side effects: Unwanted results that may happen due to treatment. The potential side effects of prostate cancer treatment include incontinence, impotence, and bowel problems.

Surgery: A procedure to remove or repair a part of the body or to find out if disease is present.

Symptom: Effect of disease as experienced by the patient. Pain, for example, is a symptom.

Transrectal Ultrasound (TRUS): The use of sound waves to produce an image of the prostate. The sound waves are produced by an instrument inserted into the rectum. As the waves bounce off the prostate, they create a pattern that is converted by a computer into a picture. TRUS is used to detect abnormal prostate growth and to guide a biopsy of the abnormal prostate area.

Tumor: Abnormal growth of tissue. Tumors can be malignant (cancerous) or benign (not cancerous).

Urethra: The tube that extends from the bladder to the tip of the penis. It carries urine from the bladder and, during ejaculation, semen from the prostate gland, out through the penis.

Urination problems: Can include frequent or painful urination, sudden urges to urinate, bloody urine, or not being able to control urination (i.e., leaking urine).

Urologist: A doctor (surgeon) who specializes in disorders of the urinary system and the male reproductive system.

Watchful Waiting: Following the patient closely with frequent PSA tests and postponing active treatment unless symptoms or other signs of disease become apparent. Watchful waiting can be a choice for monitoring both an enlarged prostate and early-stage prostate cancer.

Definitions adapted from Understanding Prostate Changes: A Health Guide for All Men, National Cancer Institute, August 2004, NIH Publication No. 02-5199; What You Need to Know About Prostate Cancer, National Cancer Institute, May 2005, NIH Publication No. 05-1576; and the American Cancer Society's cancer glossary at www.cancer.org.

Selected References for Related Articles

Fay, M.P., Pfeiffer, R., Cronin, K.A., Le, C. and Feuer, E.J. (2003). Age-conditional probabilities of developing cancer. Statistics in Medicine, 22(11): 1837-1848.

Gattellari, M., Ward, J.E. (2003). Does evidence-based information about screening for prostate cancer enhance consumer decision-making? A randomized controlled trial. Journal of Medical Screening, 10, 27-39.

Harris, R., Lohr, K.N. (2002). Screening for prostate cancer: An update of the for the U.S. Preventive Services Task Force. Annals of Internal Medicine, 137(11): 917-933.

Litwin, M.S. (1999). Health related quality of life in older men without prostate cancer. The Journal of Urology, 161: 1180-1184.

National Center for Health Statistics, http://209.217.72.34/HDAA/TableViewer/tableView.aspx? ReportId=129 (for mortality data presented on page 22)

Penson, D.F., Feng, Z., Kuniyuki, A., et al. (2003). General quality of life 2 years following treatment for prostate cancer: What influences outcomes? Results from the Prostate Cancer Outcomes Study. Journal of Clinical Oncology, 21(6): 1147-1154.

Potosky A.L., Davis W.W., Hoffman R.M., Stanford J.L., Stephenson R.A., Penson D.F., Harlan L.C. (2004). Five-year outcomes after prostatectomy or radiotherapy for prostate cancer: the prostate cancer outcomes study. J Natl Cancer Inst. 96(18):1358-67.

Potosky, A.L., Legler, J., Albertsen, P.C., et al. (2000). Health outcomes after prostatectomy or radiotherapy for prostate cancer: Results from the Prostate Cancer Outcomes Study. Journal of the National Cancer Institute, 92(19): 1582-1592.

Schapira, M.M., Lawrence, W.F., Katz, D.A., McAuliffe, T.L., Nattinger, A.B. (2001). Effect of treatment on quality of life among men with clinically localized prostate cancer. Medical Care, 39(3): 243-253.

Schwartz, K., Bunner, S., Bearer, R., Severson, R.K. (2002). Complications from treatment for prostate carcinoma among men in the Detroit area. Cancer, 95 (1): 82-89.

Steineck, G., Helgesen, F., Adolfsson, J., Dickman, P.W., Johansson, J., Norlen, B.J., Holmberg, L. (2002). Quality of life after radical prostatectomy or watchful waiting. New England Journal of Medicine, 347 (11): 790-796.

Thompson, I.M., Pauler, D.K., Goodman, P.J., et al. (2004). Prevalence of prostate cancer among men with a prostate-specific antigen level 4.0 ng per milliliter. The New England Journal of Medicine, 350 (22): 2239-2246.

Contact Information for National Organizations

For more information on prostate cancer screening, treatments, and studies, please contact the organizations below. Although these organizations may either recommend for or against screening, all recommend shared decision making with your doctor.

American Academy of Family Physicians
800-274-2237 *or* www.aafp.org

American Cancer Society
800-227-2345 *or* www.cancer.org

American College of Physicians
800-338-2746 *or* www.acponline.org

American College of Preventive Medicine
800-523-1546 *or* www.acpm.org

American Foundation of Urologic Disease
866-746-4282 *or* www.auafoundation.org

American Medical Association
800-621-8335 *or* www.ama-assn.org

American Urological Association
866-746-4282 *or* www.auanet.org

Centers for Disease Control and Prevention
800-311-3435 *or* www.cdc.gov

European Randomized Screening for Prostate Cancer Trial
(Web site only) www.erspc.org

National Cancer Institute (NCI)
800-422-6237 *or* www.cancer.gov

National Medical Association
202-347-1895 *or* www.nmanet.org

National Prostate Cancer Coalition
888-245-9455 *or* www.pcacoalition.org

NCI's Prostate Cancer Outcomes Study
800-422-6237 *or*
www.cancer.gov/newscenter/pcos

NCI's Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial
800-422-6237 *or*
http://prevention.cancer.gov/programs-resources/groups/ed/pro

Oncolink
(Web site only) www.oncolink.upenn.edu

Prostate Cancer Education Council
866-477-6788 *or* www.pcaw.com

U.S. Preventive Services Task Force
301-427-1364
www.ahrq.gov/clinic/uspstfix.htm

US TOO Cancer Education and Support
800-808-7866 *or* www.ustoo.com

This information was developed by researchers at Georgetown University (NIH Grant #1ROI CA119168-01 and the Department of Defense Prostate Cancer Program Award No. W81XWH-06-1-0182), with content adapted from Prostate Cancer Screening Making an Informed Decision (1 R01 CA 098967-01) and from *Prostate Cancer Screening: A Decision Guide*, published by the Centers for Disease Control and Prevention (CDC). Additional information was obtained from published research studies.

Information in this booklet is accurate at the time of printing (August 2007). Research currently underway may change its contents.

Suggested Citation: Taylor, K.L., Davis, K.M., Schwartz, M.D., Goldman, P.H., Dawson, D.L., Ohene-Frempong, J., Woolf, S.H., Krist, A., Fishman, M.B., Cole, C.A., Red, S., Parker, E., Dorfman, C. and Haisfield, L. (2007) *Prostate Cancer Screening: Making the Best Choice* (patient decision aid). Georgetown University Medical Center, Washington, DC.

Lombardi Comprehensive Cancer Center

Georgetown University Medical Center

Georgetown University Hospital

Washington Hospital Center