

Prostate Cancer
Minimal Elements for Information, Screening, Diagnosis, Treatment, and Follow up
Center for Cancer Surveillance and Control
Maryland Department of Health and Mental Hygiene
July, 2002; Revised May 2005; Revised May 2010

Summary of major updates or decisions by the Medical Advisory Committee compared to the prior version of the Prostate Minimal Elements, 2005

- Updated the information a man should be given for informed decision making (page 1 and Fact Sheet, Prostate Cancer: Is Screening Right for You, page 10).
- Placed the information about testing in a flow sheet (page 6).
- Added new information about factors that can affect the PSA level including timing of DRE, ejaculation, and certain medications (pages 1, 2, 3, 4, 7, and 8).
- Clarified age for prostate screening: Offer baseline PSA test and DRE to men at age 40 years; stop screening men age ≥ 75 years.
- Added information about obtaining a baseline PSA at age 40.
- Added information about the frequency of PSA and DRE testing in men between age 40 and 49 years, based on PSA test results and PSA velocity (page 6).
- Added the interpretation of elevated PSA velocity *based on the level of PSA* (page 8):
 - Velocity ≥ 0.35 ng/mL/year is “elevated velocity” if PSA is <4.0 ng/mL;
 - Velocity > 0.75 ng/mL/year is “elevated velocity” if PSA is 4.0-10.0 ng/mL;
 - Velocity is not meaningful if PSA is > 10.0 ng/mL; this PSA level is suspicious for cancer regardless of the velocity.
- Updated the follow-up of screening findings based on the above changes (pages 6).
- Clarified that “referral to a urologist for evaluation of abnormal findings” should also be based on whether there has been a *prior* referral to urologist. If so, the Medical Case Manager may take into account the urologist’s prior recommendation for future management and additional testing (page 4 top, and footnote page 6).
- Clarified when CRF programs may pay for bone scans and pelvic CT or MRIs (page 4).
- Deleted the attachment of staging that gave the prostate cancer stage based on tumor, nodes, and metastasis.
- Updated the membership of the Prostate Cancer Medical Advisory Committee (page 9).

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The following Minimal Elements are based on medical and epidemiologic information available to the DHMH Prostate Cancer Medical Advisory Committee at the time of their discussions beginning in the spring, 2002, and updated in May 2005, and in May 2010. The Prostate Minimal Elements will continue to be updated as medical information and recommendations of other agencies change.

A screening program or site should, in the process of informed decision making, give the following *minimum information* to each man *before* offering screening:

- Screening for prostate cancer is for men who have not had prostate cancer in the past.
- Incidence and mortality from prostate cancer: Prostate cancer is the most common cancer in men, and is the second leading cause of cancer deaths in men.
- Certain men are at higher risk of prostate cancer: Men of African descent, men with a father, brother, or son with prostate cancer, and older men are at higher risk.
- Men may benefit from having a baseline PSA test at age 40 with the frequency of PSA thereafter based on the baseline PSA level.
- Those who will benefit most from prostate cancer screening are men 50-69 years of age with at least a 10 year life expectancy.
- The digital rectal exam (DRE) is where a doctor feels the prostate gland by putting a finger inside the rectum.
- The PSA (prostate specific antigen) is a blood test used to screen for prostate cancer in men without symptoms and to monitor men with prior prostate cancer.
- The PSA is done along with a DRE to screen for prostate cancer.
- The PSA test can find prostate cancer earlier than the DRE alone.
- The PSA test can be high because of other prostate problems, so it does not always mean cancer. The PSA can be elevated because of recent ejaculation or if a DRE is done just before the PSA.
- The PSA test can sometimes be normal even if a man has prostate cancer.
- Certain prostate medications (finasteride [for example, Proscar or Propecia], dutasteride [for example, Avodart], and androgen receptor blockers) can lower a man's PSA level.
- A PSA test that is high or a PSA velocity that is rising may lead to a recommendation for biopsy of the prostate gland to see whether a man has prostate cancer; a biopsy may have complications.
- No one is sure yet whether getting a DRE and PSA test every year will reduce the number of deaths from prostate cancer, but some information now suggests that these screening tests may lower the number of deaths.
- A man who has early prostate cancer can choose how to handle the cancer—he and his doctor may choose “active surveillance” to see if the prostate cancer is changing, or he may choose to be treated with surgery, radiation therapy, and/or hormonal therapy.
- If a man chooses to have treatment, there are often side effects of the treatment.

- If a man has a PSA and/or a DRE, he will get the results of his tests and have a chance to talk to someone knowledgeable about what the results mean and what his options are.

Location of screening

- Either at a primary care provider's office, a urologist's office, or at a screening site outside of the clinical arena (e.g., community settings or health fairs).

A screening site must include the following aspects:

- Determine program eligibility and bill third party payers if a man has insurance that covers prostate cancer screening;
- Test with both PSA and DRE at the same screening, **or** if screening with DRE is not feasible at the same site and time of the PSA testing, then test with PSA followed by the opportunity for a DRE at another site and time. If DRE is not available at the time of PSA testing, programs should have an established plan for how a client will be educated about the need for DRE to complete his screening and about how a client will have his DRE facilitated through prearranged plans for clinic sites, times, and transportation;
- Provide the opportunity for a man to participate in the decision-making about whether to be screened;
- Provide information about prostate cancer and screening for prostate cancer as listed above (pages 1 and 10);
- Allow time for client to read or view information, formulate questions, and have questions answered by a knowledgeable person before and after testing;
- Obtain written, signed, informed consent for screening;
- Provide a private location where questions can be asked and answered in confidence without being heard by others;
- Provide a private location for performing DRE;
- Maintain confidentiality of the results of the DRE and blood test;
- Provide information about how the man will receive results;
- Have a carefully worked out plan that establishes how the man and his primary care physician (if the man names one) will receive his results within 5 weeks of screening; and
- Assure notification of results to a man with *abnormal* test results for age including at a minimum those with DRE suggestive of prostate cancer, a PSA elevated for age (see page 7), or an elevated PSA velocity (see page 8). Notify verbally and send written confirmation of results. Use certified letter requiring signature when unable to contact the client with results by telephone or regular mail.

A screening site *outside of the clinical arena* must *additionally* have:

- A protocol for case management of the man based on his test results;
- A provider who is responsible for the entire screening "event;"
- Licensed and insured clinical staff (M.D., N.P., or P.A.) who performs the DREs;
- A physician who will review the age, race, family history, DRE results, and PSA test results and make a clinical recommendation for next steps;
- Names and phone numbers of at least one clinician to whom men may be referred for follow-up, if needed;

- A method of data collection, recording, and retrieval that captures demographics, dates, and results of prostate cancer screening tests so that PSA velocity can be calculated (see page 8) on a man who returns multiple times for screening;
- Payment for diagnosis and treatment or referral for diagnosis and treatment for a man with *abnormal* screening results, as follows:
 - if the man has insurance or is not program eligible, then refer to a source of care; or
 - if a man is eligible under the local Cancer Prevention Education, Screening, and Treatment Program of the Cigarette Restitution Fund (CRF) grant for treatment services (by residence, income, insurance, etc.), then either:
 - pay for diagnosis and treatment if the local program has sufficient funds and will cover the specific services (either direct payment to providers or payment for Maryland Health Insurance Premiums/co-payments/deductibles);
 - pay for diagnosis and treatment using Maryland Cancer Fund funds (either payment for Maryland Health Insurance Premiums/co-payments/deductibles or direct payment to providers); or
 - have a prearranged method for follow-up and referral to appropriate care providers for diagnosis and treatment.

Sample letters for the men screened and for provider referrals are available from DHMH.

Tip: Having the man address his own envelope in which the program will mail the screening results may speed the notification process.

Other considerations for screening

- If a man who meets the age and risk criteria listed below asks the screening site personnel whether he should be screened *after* he has been given information and had a chance to have his questions and those of his spouse/partner answered, the testing site should recommend screening.
- If possible, draw blood for PSA test before performing DRE.
- Ejaculation: PSA test results are more reliable if the man has abstained from ejaculation for 48 hours. If the man ejaculated within 48 hours before the specimen was drawn and the original sample was marginally elevated, repeat PSA after the man abstains from ejaculation for 48 hours.
- Medicines that affect PSA:
 - Finasteride (e.g., Proscar or Propecia) and dutasteride (e.g., Avodart) can lower the PSA. (In patients using these drugs, failure to have a substantial decrease [approximately 50%] in PSA or having an increase while on medication can be associated with an increased risk of prostate cancer.)
 - Androgen receptor blockers.

- A man who has had a **PSA test within the past year** should not be initially screened by the screening program, but should be referred back to his prior provider for follow-up. (A man who is screened in the program and recommended for PSA in less than 12 months may be screened in the program at the recommended interval.)
- A man who requests **PSA test without DRE** at a site where both are being offered (or vice versa) should not be refused a PSA test; **however**, the site should counsel him about the rationale for testing with both DRE and PSA test, and encourage him to have both tests. If a man still chooses not to have a DRE, the site should **document the counseling and the man's refusal of the DRE in writing, and have the man sign his request on the informed consent sheet.**
- If client was referred to urologist in the past for PSA elevation or abnormal DRE, then the Medical Case Manager should follow the urologist's guidance regarding the findings that would signal the level of PSA of concern, the need to return to the urologist for evaluation, the timing of subsequent repeat PSAs, the need for biopsy, etc.
- Studies have not shown value in annual PSA testing for men who maintain PSA levels that are normal or below normal for age. Consider testing PSA **less frequently** than annually in men under 75 years of age who maintain PSA levels that are normal or below normal for age.

Screening Recommendation, Result Categories, and Follow up of Screening Findings

- Detection for a man **40 through 74 years old**:
 - **Obtain DRE results, PSA Level, and PSA Velocity from clinician and/or lab.**
 - **Interpret results and determine recommendations based on the following flow sheet and charts:**
 - See flow, page 6;
 - See interpretation of PSA Level based on Age, page 7;
 - See interpretation of PSA Velocity based on PSA level, page 8.
- Detection for a man ≥ 75 years old:

Screening with PSA is not recommended. The man may be referred to his primary care provider for discussion of the risks and benefits of screening.

Diagnosis / Further Evaluation

- Based on the DRE and PSA, **additional testing may be indicated for evaluation and staging** per the urologist or other medical case manager using protocols such as the National Comprehensive Cancer Network (NCCN), or the American Urological Association.
- CRF programs **may pay** for the following tests **if life expectancy is >5 years or man is symptomatic, and the following indications are present:**

Test	Indications for Payment in CRF Program
Bone scan	One or more of the following: T4; T3; T1 or T2 with a PSA level of >20ng/mL; Gleason score \geq 8; or Symptomatic with bone pain
Pelvic CT or MRI	One or more of the following: T4; T3; or T1 or T2 with nomogram indicating probability of lymph node involvement >20% (see Reference 6).

Histologic Classification of Tumor

- A specimen should be classified by its Gleason score.

Staging

- The urologist should report the:
 - **Clinical characteristics of the tumor (T), nodes (N), and metastasis (M),** and
 - **Pathologic TNM Stage** if there is a prostatectomy specimen.

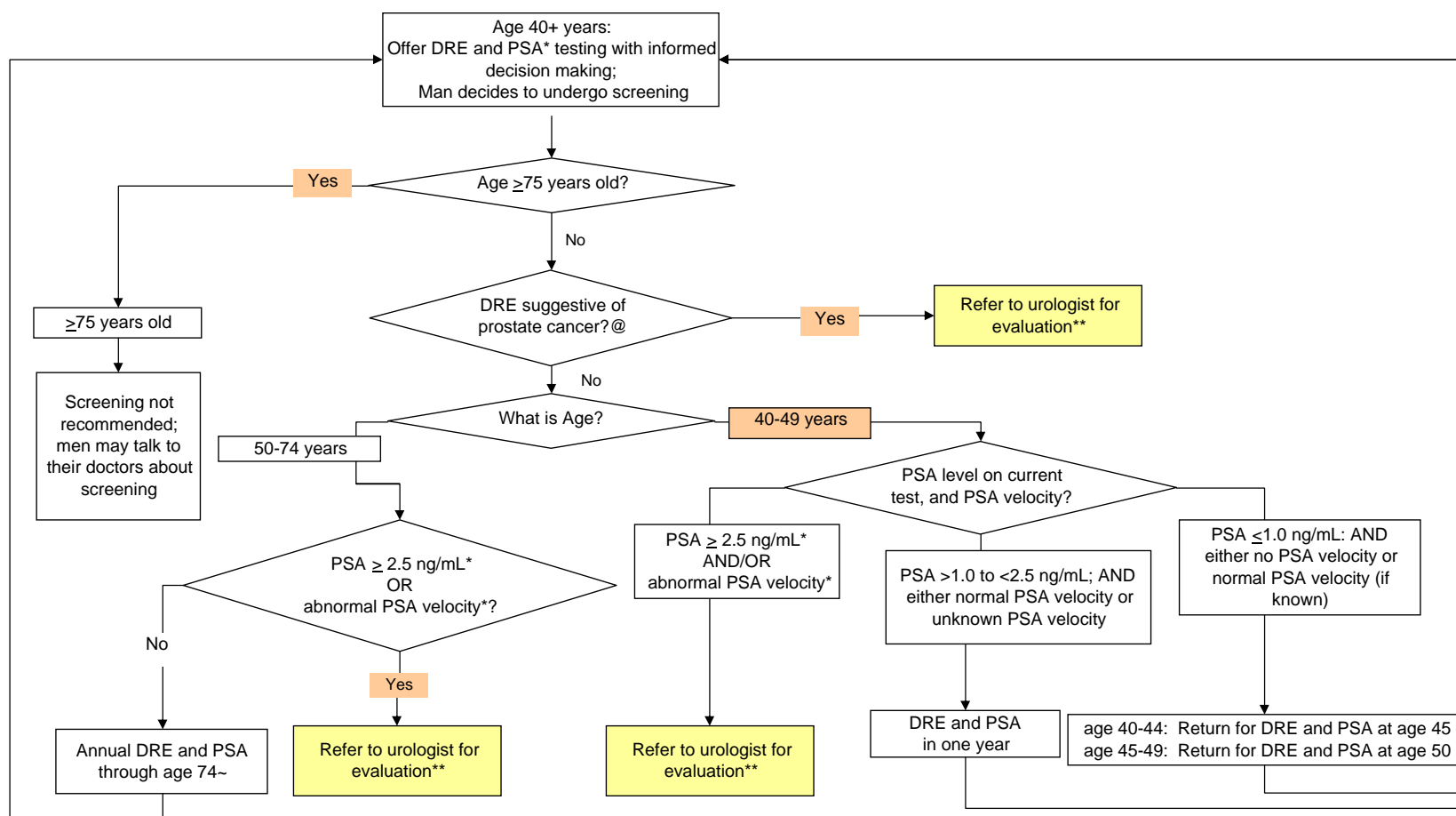
Management

- Based on the findings on DRE, PSA, transrectal ultrasound (TRUS), other screening/diagnostic tests, and further evaluation and consultation, the urologist will recommend, on a case-by-case basis, management using protocols such as the NCCN, or American Urological Association, and future PSA testing.

References:

1. Smith RA, Cokkinides V, and Brawley OW. Cancer screening in the United States, 2009: A review of current American Cancer Society guidelines and issues in cancer screening. CA Cancer J Clin, Jan 2009; 59(1): 27 – 41.
2. Greene KL, Albertsen PC, Babaian RJ, et al. Prostate specific Antigen Best Practice Statement: 2009 Update. J Urology, Nov 2009; 182 (5), 2232-41.
3. National Comprehensive Cancer Network [NCCN] V.2.2010, Prostate Cancer Early Detection (http://www.nccn.org/professionals/physician_gls/PDF/prostate_detection.pdf).
4. National Comprehensive Cancer Network [NCCN] V.1.2010, Prostate Cancer (http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf).
5. Andrew MD, Wolf AMD, Wender RC, Etzioni RB, et al. American Cancer Society Guideline for the Early Detection of Prostate Cancer--Update 2010. CA Cancer J Clin 2010;60:70–98.
6. Prostate nomogram examples:
<http://urology.jhu.edu/prostate/partintables.php>
<http://www.prostatecancer-riskcalculator.com/via.html>

Flow Chart of PSA* and DRE Screening and Management Maryland, May 2010



* See Pages 7 and 8 for information on PSA levels and PSA velocity.

** Refer to urologist for evaluation; **however**, if the client was referred to a urologist in the past for PSA elevation or abnormal DRE, then the Medical Case Manager should follow the urologist's guidance regarding the findings that would signal the level of PSA of concern, the need to return to the urologist for evaluation, the timing of subsequent repeat PSAs, the need for biopsy, etc.

@ if DRE is *abnormal but NOT suggestive of cancer*, proceed with interpretation of PSA to determine referral to urologist for workup of prostate cancer. If PSA is normal for age/race/family history, but DRE is abnormal but NOT suggestive of cancer (for example, benign prostatic hyperplasia [BPH], anal or rectal cancer, hemorrhoids, etc.), refer the man for follow up as appropriate but not within the prostate cancer program.

~ Studies have not shown value in annual PSA testing for men who maintain PSA levels that are normal or below normal for age. Consider testing for PSA less frequently than annual in these men.

**Prostate Specific Antigen (PSA) Interpretation BY AGE
for a Man without Prior Prostate Cancer**

PSA Level *	Interpretation of PSA Level *
AGE 40-49 Years	
< 1.0 ng/mL	Normal PSA level (that is, not elevated for age)
> 1.0 ng/mL to <2.5 ng/mL	PSA level in upper range for age
≥ 2.5 ng/mL	Elevated PSA level for age
AGE 50 Years and Older	
<2.5 ng/mL	Normal PSA level (that is, not elevated for age)
≥ 2.5 ng/mL	Elevated PSA level for age

*** Notes about PSA:**

PSA levels are a continuum. Interpretation imposes arbitrary thresholds to signify level of risk based on age and level of PSA.

If a man had a prior PSA test, check level and calculate PSA velocity and compare to the chart below.

If possible, **draw PSA before DRE.**

Ejaculation: PSA test results are more reliable if the man has abstained from ejaculation for 48 hours. If the man ejaculated within 48 hours before the specimen was drawn and the original sample was marginally elevated, repeat PSA after the man abstains from ejaculation for 48 hours.

Medicines that can lower the PSA:

- Finasteride (for example, Proscar and Propecia) and dutasteride (for example, Avodart). (In patients using these drugs, failure to have a substantial decrease [approximately 50%] in PSA or having an increase while on medication can be associated with an increased risk of prostate cancer.)
- Androgen receptor blockers.

PSA in man *with* prior prostate cancer: A urologist should interpret the PSA value in a man with prior diagnosis of prostate cancer; this chart is not applicable to that evaluation.

PSA Velocity Interpretation **

Lowest PSA in the time interval in which velocity is being calculated	PSA Velocity Elevated and Suspicious for Cancer
PSA < 4.0 ng/mL	PSA velocity of ≥ 0.35 ng/mL/year is elevated and suspicious for cancer
PSA 4.0--10.0 ng/mL	PSA velocity of ≥ 0.75 ng/mL/year is elevated and suspicious for cancer
PSA >10 ng/mL	Velocity is not useful; PSA >10 ng/mL is suspicious for cancer <u>regardless</u> of the velocity

** Notes about PSA velocity:

(ref: NCCN Prostate Cancer Early Detection v.2.2010, page {RPSD-5})

"PSA velocity" is the rate of increase of the PSA level over time and is expressed as ng/mL/year. PSA velocity is calculated for a man who has had at least **three** consecutive specimens drawn over at least an 18-24 month interval. The PSA velocity is calculated between the first and second results, and the second and third results, etc. The average of these velocities is then considered the PSA velocity. The interpretation of "elevated PSA velocity" depends on the PSA level from which it was calculated: PSA velocity is interpreted based on the man's lowest PSA level (column 1 of above chart) that was used in calculating the PSA velocity.

For example, a man's first PSA is 1.0 ng/mL. His second PSA **12 months later** is 2.0 ng/mL. Because of this rise, he has a third PSA **6 months later** which has risen to 3.0 ng/mL. The first PSA velocity is **1 ng/mL/year**; the second PSA velocity is 1.0 ng/mL / **6 months** or **2 ng/mL/year**; the average of these two is $(1+2)/2$ or **1.5 ng/mL/year**.

Based on the chart, and because the lowest PSA used in this calculation was <4.0 ng/mL, the PSA velocity of 1.5 ng/mL/year is greater than 0.35 ng/mL/year so the interpretation of the PSA velocity is "elevated and suspicious for cancer."

Biologic variability and/or prostatitis may be confounding factors in determining PSA velocity, therefore, antibiotic therapy and repeated PSA measurements should be used to minimize these sources of confusion.

Prostate Cancer Medical Advisory Committee Members, 2010

Stanley Watkins, MD, Chairman	Medical Oncologist Medical Director of Oncology Initiative Anne Arundel Medical Center Hematologist/Oncologist, Annapolis Medical Specialists Assistant Professor of Oncology The Johns Hopkins University School of Medicine (part time)
Pradip Amin, MD	Radiation Oncologist Associate Professor of Radiation Oncology Department of Radiation Oncology University of Maryland Medical Center
H. Ballentine Carter, MD	Urologist Professor of Urology, Oncology Director, Division of Adult Urology The James Buchanan Brady Urological Institute The Johns Hopkins University School of Medicine
Jonathan Epstein, MD	Pathologist Professor, Department of Pathology, Urology, and Oncology The Johns Hopkins University School of Medicine
Jean Ford, MD	Director, Community-based Research The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins The Johns Hopkins Bloomberg School of Public Health
Ann Klassen, PhD	Epidemiologist Associate Professor, Dept. of Health Policy and Management The Johns Hopkins Bloomberg School of Public Health and Department of Oncology The Johns Hopkins University School of Medicine
Boris Naydich, MD	Radiation Oncologist and Medical Director Chesapeake Potomac Regional Center Care, Holy Cross Hospital and Washington Hospital Center, Waldorf Radiation Oncology Center, Waldorf, MD Charlotte Hall Radiation Oncology Center, Charlotte Hall, MD
Elizabeth A. Platz, ScD, MPH	Epidemiologist Professor, Dept. of Epidemiology The Johns Hopkins Bloomberg School of Public Health
David P. Zajano, MD	Family Medicine Chairman, Department of Family Practice, Franklin Square Hospital Center Baltimore, Maryland
Donna Gugel, MHS, Director Diane M. Dwyer, MD, Medical Director Catherine Musk, RN, MS, Nurse Consultant	Maryland Dept. of Health and Mental Hygiene Center for Cancer Surveillance and Control Baltimore, Maryland

Prostate Cancer: Is Screening Right for You?

- Prostate cancer is the most common cancer in men. It is the second leading cause of cancer deaths in men.
- Certain men are at higher risk of prostate cancer:
 - African American men, men of African descent, men who have a father, brother, or son with prostate cancer, and all men over 50 are at higher risk.
- There are two tests that screen a man for prostate cancer: PSA and DRE.
 - The PSA (prostate specific antigen) is a blood test for prostate cancer.
 - The DRE (digital rectal exam) is where a doctor feels the prostate gland by putting a gloved finger inside the rectum.
 - The PSA is done along with a DRE to screen for prostate cancer.
 - The PSA test can find prostate cancer earlier than the DRE alone.
- The PSA test result can be high because of *other* prostate problems--so an elevated PSA does *not* always mean cancer. PSA can be higher because a man ejaculated in the 1-2 days before the test. Also, the PSA test results can sometimes be normal even if a man has prostate cancer. Certain medicines can lower the PSA test results.
- Men may benefit from having a “baseline” PSA test at age 40, especially men at higher risk of prostate cancer. The frequency of PSA testing is then based on the baseline PSA result.
- Men who will benefit most from prostate cancer screening are 50-69 years of age who have at least a 10 year life expectancy. Men 75 years of age or older should talk to their doctors before screening.
- No one is sure yet whether getting a DRE and PSA test every year will lower the number of deaths from prostate cancer. Some information now suggests that prostate screening tests may lower the number of deaths.
- If a man has a PSA and a DRE test, he will get the results of the tests. If either of the tests is abnormal, he will be referred to a doctor who will explain what the results mean and what his options are.
- A PSA test result that is high may lead a doctor to recommend a biopsy to see if the man has prostate cancer. The biopsy may cause side effects. The biopsy and treatment may or may not be paid for by the local cancer program.
- If a man has early prostate cancer, he can choose how to handle the cancer.
 - He and his doctor may choose to wait and see if the prostate cancer is changing.
 - He may choose to have surgery, radiation therapy, or hormonal therapy.
 - There are often side effects of the treatment(s).

If you don't get your results in **6 weeks** after you have the test, call the prostate cancer screening program at _____ for your results.