

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

Summary of Major Updates or Decisions by the Medical Advisory Committee:

- Expanded the men who may benefit from prostate cancer screening to include those men 40-45 years of age who:
 - a. are African American (or of African descent) *and* who have one or more first degree relatives with prostate cancer; or
 - b. are of any race and have **two** first degree relatives with prostate cancer diagnosed before the age of 65.

Subsequent testing would be guided by these baseline results.

- **Allow screening sites to offer PSA blood testing alone** for prostate screening where DRE is not feasible on site; the DRE should then be offered to men and arranged for them at another time and location.
- Changed the interpretation of a PSA of **2.5 ng/mL to 3.9 ng/mL to “Borderline abnormal” for men with average risk**; recommended that these men also be referred to a urologist for follow-up.
- Noted that a prostate cancer should be classified by its Gleason score.

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The following Minimal Elements are based on medical and epidemiologic information available to the DHMH Prostate Cancer Medical Advisory Committee (see page 9) at the time of their discussions in the spring, 2002 and updated in May 2005. These 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:

- 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
- Those who will benefit most from prostate cancer screening are:
 - men 50 to 70 years of age;
 - men 45 to 49 years of age who:
 - are African American or of African descent, *or*
 - have a first degree relative (father, brother, or son) with prostate cancer
 - men 40-45 years of age who:
 - are African American or of African descent **and** who have one or more first degree relatives with prostate cancer; or
 - are of any race and have **two** first degree relatives with prostate cancer diagnosed before the age of 65.
- 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 for 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
- And, the PSA test can sometimes be normal even if a man has prostate cancer
- A PSA test that is high may lead to a 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 to wait and watch to see if the prostate cancer is changing, or he may choose to be treated with surgery, radiation therapy, 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 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:

- testing 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 testing 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.
- opportunity for a man to participate in the decision-making about whether to be screened
- information about prostate cancer and screening for prostate cancer as listed above
- time to read or view information, formulate questions, and have questions answered by a knowledgeable person before and after testing
- written, signed, informed consent for screening
- a private location where questions can be asked and answered in confidence without being heard by others
- a private location for performing DRE
- confidentiality of the results of the exam and blood test
- information about how the man will receive results
- 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 6 weeks of screening
- a registered letter, at a minimum, to a man with abnormal test results

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

- a protocol for case management of the man based on his test results
- a provider who is responsible for the entire screening "event"
- licensed 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 results and make a clinical recommendation for next steps
- names and phone numbers of at least one clinician to whom patients 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 (see below) can be calculated 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 a man is eligible under the local Cancer Prevention Education, Screening, and Treatment Program of the Cigarette Restitution Fund (CRF) grant, then either
 - payment for diagnosis and treatment if the local program has sufficient funds and will cover the specific services,
 - or

- a prearranged method for follow-up and referral to appropriate care providers for diagnosis and treatment; or
- if the man has insurance or is not program eligible, then referral to a source of care.

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

Tip: Having a participant address his own envelope for mailing 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.**
- A man who has had a **PSA within the past year** should not be screened, but should be referred back to his prior provider for follow-up.
- A man who requests **PSA without DRE** at a site where both are being offered (or vice versa) should not be refused testing with PSA; **however**, the site should counsel him about the rationale for testing with both DRE and PSA, 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.**

Screening Recommendation

- Detection for a man **50 to 70 years old *without*** other race or family history risk factors:
 - Screen with PSA and DRE**
- Detection for a man **45 to 49 years old who**
 - is either African American, of African descent, or
 - has a family history of prostate cancer in father, brother, or son:
 - Screen with PSA and DRE**
- Detection for a man **40 to 44 years old who:**
 - is African American or of African descent *and* has one or more first degree relatives with prostate cancer, *or*
 - is of any race and has *two* first degree relatives with prostate cancer diagnosed before the age of 65 years:
 - Programs have the flexibility to screen once with PSA and DRE beginning at age 40 and have the results guide future testing/management (see below)**

- Detection for a man >70 years old

Refer the man to his primary care provider for discussion of the risks and benefits of screening and the decision on testing. A man who has no primary care provider can be given referral information for providers where he may seek information on prostate cancer screening.

Result categories:

- **DRE:**
 - Negative exam
 - Abnormal exam—suggestive of prostate cancer
 - Abnormal exam—not suggestive of prostate cancer
- **PSA level:** result in ng/mL

Normal PSA or Elevated PSA based on PSA level, race, and family history; see table below:

PSA Level (in ng/mL)	Race and family history risk factors	
	Increased Risk A man who is African American, or of African descent, or A man with prostate cancer in his father, brother, or son	Average Risk None of the risk factors listed to the left
<2.5	Normal PSA level*	Normal PSA level*
2.5 to < 4	Elevated PSA level	Borderline Elevated PSA level*
≥ 4	Elevated PSA level	Elevated PSA level

* If a man has had **previous** PSA tests, check to see if **PSA velocity** is also normal (see below)

- **PSA velocity:** result in ng/mL/year
(ref: NCCN Prostate Cancer Early Detection v.1.2001)
“PSA velocity” is the rate of increase of the PSA level over time. It is calculated in a man who has had at least three tests over at least an 18-month period and whose PSA levels are increasing over time, but may still be in the normal range. The 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.

Normal PSA velocity: <0.75 ng/mL/year
Abnormal PSA velocity: ≥0.75 ng/mL/year

Follow up of screening findings:

- Any age with
 - abnormal DRE suggestive of prostate cancer;
 - elevated PSA (see above);
 - borderline elevated PSA (see above); *or*
 - abnormal PSA velocity (see above):
Refer to a urologist for further evaluation based on protocols such as the National Comprehensive Cancer Network (NCCN), or American Urological Association.
- 45 years and older with normal DRE *and* normal PSA *and* normal PSA velocity (if available):
Recommend annual testing with DRE and PSA; calculate PSA velocity
- 40-44 years old with PSA ≥ 1.0 ng/mL but <2.5 ng/mL:
Recommend annual testing with DRE and PSA; calculate PSA velocity
- 40-44 year old with PSA of <1.0 ng/mL
Return for PSA and DRE testing at age 45
- Any age with other findings (including Abnormal DRE—not suggestive of prostate cancer)
If PSA is normal (and PSA velocity is normal, if available) but other medical conditions are found (benign prostatic hyperplasia [BPH], anal or rectal cancer, hemorrhoids, etc.) that are not covered by the local cancer program, refer the man for follow up as appropriate.

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 NCCN, or American Urological Association; however,
CRF programs **should not pay for** a bone scan in a man whose PSA is <10 ng/mL, or for any CT scan, or any MRI, because these tests are not indicated.

Histologic Classification of Tumor

- A specimen should be classified by its Gleason score

Staging

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

Modified* from American Joint Committee on Cancer (AJCC) TNM Staging System for Prostate Cancer, Sixth Edition, 2002

AJCC*				Comparison to SEER and Maryland Cancer Registry Classification
Stage	Tumor (T)	Regional Lymph Nodes (N)	Distant Metastasis (M)	
Stage I	T1a,	N0	M0	Local
Stage II	T1a, T1b,1c, T1, T2	N0	M0	
Stage III	T3	N0	M0	Regional
Stage IV	T4	N0	M0	
	Any T	N1	M0	
	Any T	Any N	M1	Distant

Definition of TNM

- TX Primary tumor cannot be assessed
- T0 No evidence of primary tumor
- T1 Clinically inapparent tumor not palpable nor visible by imaging
 - T1a Tumor incidental histologic finding in 5% or less of tissue resected
 - T1b Tumor incidental histologic finding in more than 5% of tissue resected
 - T1c Tumor identified by needle biopsy (e.g., because of elevated PSA)
- T2 Tumor confined within prostate
- T3 Tumor extends through the prostate capsule
- T4 Tumor is fixed or invades adjacent structures other than seminal vesicles: bladder neck, external sphincter, rectum, levator muscles, and/or pelvic wall.

- NX Regional lymph nodes cannot be assessed
- N0 No regional lymph node metastasis
- N1 Metastasis in regional lymph node(s)

- MX Distant metastasis cannot be assessed
- M0 No distant metastasis
- M1 Distant metastasis

* AJCC 2002 staging includes reference to Histologic Grades 1-4; this grading system is no longer being used. A specimen should be classified by its Gleason score.

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