PSA Pre-screening Information

The National Comprehensive Cancer Network (NCCN) has issued new guidelines for prostate cancer screenings. The guidelines were developed from a systematic literature review to ensure that men most likely to benefit from early detection are screened, and to encourage shared decision-making between the patient and physician:

Men who are considering PSA screening should now speak with their physician about the benefits and harms of testing to determine the best course of action.

Screening is for healthy men without a personal history of prostate cancer. Men with known prostate cancer should follow up with their diagnosing physician or seek consultation from a urologist.

Prostate cancer screening is not recommended for men <45 years of age, or those > 75 years old or with less than 10-15 years life expectancy. Men who are at higher risk of prostate cancer (race, family history, etc.) may be eligible to screen earlier starting at age 40.

To reduce the harms of screening, a routine screening interval of two years or more may be preferred over annual screening in those men who have participated in shared decision-making and decided on screening.

Prostate cancer is the most common malignancy and the second most common cause of cancer death in American men. The Prostate Specific Antigen (PSA) blood test and the digital rectal examination (prostate exam or DRE) may help identify prostate cancer in an early stage. This concept; however, has not been scientifically proven and is currently the subject of great debate. All men should be aware of the risks and benefits of screening including, but not limited to the following:

**Possible Benefits:** Finding prostate cancers that may be at high risk of spreading, so that they can be treated before they spread. In some men this may lower the chance of death from prostate cancer.

**Possible Risks:** The potential risks of the PSA test are largely related to the choices made based on the test results, such as the decision to undergo further testing and treatment for prostate cancer. These risks include:

- **False positive test results:** This occurs when a man has an abnormal PSA test but does not have prostate cancer. False positive test results can lead to "unnecessary" tests, like a biopsy of the prostate.
- **Biopsy complication:** A biopsy is a procedure that carries its own risks, including pain, bleeding and infection.
- **Psychological effects:** False-positive test results can cause anxiety or distress. If you are diagnosed with prostate cancer, but it appears to be a slow-growing tumor that doesn't result in illness, you may experience significant anxiety knowing it's there which can impact your treatment decisions.

**The best evidence supports the use of serum PSA for the early detection of prostate cancer.** The value of a DRE as a stand-alone test is limited, and the prediction ability of a DRE in men with a normal PSA is poor. There is some evidence to support that a combination of PSA and DRE is more effective for the early detection of prostate cancer than either test alone. A DRE should be performed in all men with an abnormal PSA to aid in decisions regarding biopsy.

As a result, you are given the option of having a DRE during your screening.

If you have an abnormal PSA, a DRE is strongly recommended and should be performed by your physician during office follow up, or will be performed during a consultation visit with a urologist for an abnormal PSA.

<table>
<thead>
<tr>
<th>Important Influencing Factors:</th>
<th>Factors that can affect the PSA level:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The change in the PSA level from one test to the other is suggestive of risk and aggressiveness.</td>
<td>Prostatitis</td>
</tr>
<tr>
<td>PSA Levels increase with age. Enlarged prostates can have higher PSA levels.</td>
<td>BPH -Benign Prostatic Hypertrophy</td>
</tr>
<tr>
<td></td>
<td>Prostate Cancer</td>
</tr>
<tr>
<td></td>
<td>PSA level can be influenced by</td>
</tr>
<tr>
<td></td>
<td>Ejaculation 48 hours prior to testing,</td>
</tr>
<tr>
<td></td>
<td>Certain Medications</td>
</tr>
<tr>
<td></td>
<td>Rigorous Exercise</td>
</tr>
</tbody>
</table>

**Prostate Cancer Treatment:**

All risks and benefits of treatment must be discussed, including active surveillance. (having no surgical or pharmacologic treatment, unless the disease becomes more aggressive.)
Urinary frequency, weak stream, do I have BPH???

Benign Prostatic Hyperplasia (BPH) is a common condition in men over 50 years of age, but may also develop in younger men. In most men, the prostate begins to enlarge in the fourth or fifth decade of life and continues to enlarge with advancing age. The cause of this enlargement has not been identified, and it does not increase or decrease your risk of prostate cancer. BPH is usually not a serious threat to your health, but it can seriously affect the quality of your life.

BPH often causes urinary frequency during the day and/or night and may cause sudden urges to urinate or urine leakage. Some men may notice a weak urinary stream and can have difficulty starting urination or difficulty in postponing urination when the urge occurs. There may be a sensation that the bladder is not emptying completely. These urinary symptoms often interfere with a good night's sleep. As a result, you may find yourself modifying your activities to be close to a bathroom. The symptoms can vary in intensity from day to day and progress at different rates in different men. To complicate matters further, the intensity is not always in proportion to the degree of enlargement. In addition, the symptoms of BPH overlap with those of other urinary problems.

Treatment must be individualized based on the cause, pattern and intensity of your type of problem. Treatment of symptomatic BPH ranges from medication in mild cases to various types of surgery for more severe cases. The medications used to treat BPH are usually taken once daily and are safe when prescribed properly and well tolerated by most men. There are several surgical techniques available to treat BPH in those men who do not respond to medication. Some of these can be performed on an outpatient or short stay basis and have low rates of complication and short recovery periods. Please talk to your doctor or urologist about these options and get their advice. If you have questions or need more information about this subject, an appointment can be made to see one of the Stony Brook urologists if desired. Please call Stony Brook Urology at 631-216-9181

For Screening Information:
631-216-9181
Prostate Cancer Screening Consent

Welcome to the Prostate Cancer Program. In order to be screened, please read the consent entirely and sign this form and complete the attached questionnaire. The screening will consist of a prostate specific antigen (PSA) blood test and an optional digital rectal exam (DRE). Please arrive no earlier than fifteen minutes prior to appointment time. Thank you.

The PSA blood test involves drawing a venous blood specimen of approximately 10 ml. (about 2 teaspoons) from you. You may eat normally. Be sure to come well hydrated as it enhances the veins for blood drawing. Please avoid ejaculation and rigorous exercise, including bicycle riding, 48 hours prior to testing; please be sure to apply pressure to the site right after the venipuncture to minimize bruising and blood loss. Remove the bandage from the site after bleeding has stopped. You may experience minor discomfort and/or occasionally, a bruise or infection may result. You may apply a cold pack or ice to site for the first 24hrs, in 15 minute intervals and warm packs thereafter. Please remove the tape/band aid from the site as soon as the blood has clotted sufficiently. This screening program will not be responsible for expenses related to any further testing or treatment if you should require it.

The DRE is performed by inserting a gloved index finger into the rectum and gently pressing against the prostate gland. The DRE may occasionally cause some discomfort and a desire to urinate which will not last long. If your examining physician finds any abnormality, we recommend you contact your personal physician or urologist for further testing. This screening program will not be responsible for expenses related to any further testing or treatment if you should require it.

The National Comprehensive Cancer Network (NCCN) recommends that all men 45 years and older, (or men with above average risk age 40-44) be offered a baseline PSA test and Digital Rectal exam for early detection and risk assessment on an individual basis. The NCCN strongly urges that all men who have taken the test and exam discuss all results with their physician regardless of the result, to discuss the benefits of testing.

If the PSA test is considered abnormal, we recommend you contact your personal physician or a urologist for consult. Please note that although some tumors may be detected by this exam, no test is completely accurate in the detection of prostate cancer. Furthermore an abnormal exam or PSA result does not necessarily imply the presence of cancer.

You will receive a mailed letter with your DRE and PSA results within a few weeks.

Consent
By voluntarily participating in this prostate cancer screening program, I recognize and accept all risks and responsibilities associated with it. I understand that this program will only screen for abnormalities of the prostate using the DRE and PSA tests and does not constitute a complete medical examination or diagnosis. I have received information regarding the benefits and risks of PSA testing and exam, and have been given the opportunity to discuss this issue prior to the testing with a licensed physician or a licensed medical professional. I understand that although some tumors may be detected by the DRE and PSA test, no test is completely accurate in the detection of prostate cancer. For diagnosis of a medical problem, I acknowledge that I must see a physician for a complete medical evaluation. I understand that the results of this screening test will be released only to me, and the health care provider, if any I indicated on this form, and that the confidentiality of all my medical records will be maintained within current legal limits. They will never be released to a third party without my written consent and access to these records will be strictly limited to those directly involved with your screening and protected from unauthorized access. I have read this consent form, fully understand its contents and agree to participate voluntarily.

PSA Alone______ PSA & DRE______

Patient Signature ___________ Witness Signature ___________ Date Signed/Witnessed ___________
Please Fill In Patient Data:

NAME:______________________________

DATE OF BIRTH:___/___/_____

AGE_____

SOCIAL SECURITY #: XXX - XX - ________

TEST NAME: PSA

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Ordering MD</th>
<th>Collected by</th>
<th>Collect: Date &amp; Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>(X) Routine</td>
<td>Massimiliano</td>
<td></td>
<td></td>
</tr>
<tr>
<td>() Stat</td>
<td>Spaliviero, MD</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Prostate Cancer Screening Questionnaire

(All information provided below will be kept confidential and protected in accordance with applicable Federal Law)

SECTION 1 (To be completed by participant)

<table>
<thead>
<tr>
<th>First Name</th>
<th>Middle Initial</th>
<th>Last Name</th>
</tr>
</thead>
</table>

Date of Birth / / Age: 

Mailing Address: Apt# 

City State Zip Code 

Phone # (____) Last 4 digits of Social Security # 

Race (Check one)

- White/Caucasian 
- Black/African-American 
- Hispanic/Latino 
- Asian/Oriental 
- Other/ Not specified 

Marital Status (Check one)

- Married 
- Single 
- Divorced 
- Widowed 

Research (Please circle Y or N)

May we contact you regarding participation in prostate cancer research studies? 

Y N

Medical History – (Please enter or circle Y or N where appropriate)

Prostate History

Please circle Y or N

Did you have a PSA test and/or rectal exam in the last 3 years? Y N

1. Ever have a Prostate Infection (Prostatitis)? Y N
2. Enlarged Prostate (BPH)? Y N
3. Prostate Surgery for BPH? Y N
4. *Prostate Biopsy..................Y* N
   *If yes, indicate year and result below
   Year Result? Negative Positive

If your results were Positive for Prostate Cancer, please indicate treatment(s) below:

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Y or N</th>
<th>If Yes, Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Brachytherapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Radiation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Hormones</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Radical Prostatectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Watchful Waiting</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Family History of Cancer

Circle Y(Yes), N(No) or ?(Unknown) for each below:

1. Father’s father had prostate cancer? Y - N - ?
2. Father’s brother(s) had prostate cancer? Y - N - ?
3. Father had prostate cancer? Y - N - ?
4. Brother had prostate cancer? Y - N - ?
5. Mother’s family had prostate cancer? Y - N - ?
6. Mother’s family had breast cancer? Y - N - ?
7. Mother had breast cancer? Y - N - ?

Have you ever had any genetic tests for Prostate Cancer? Y N

PCA3, urine test: Y N
4KScore, Blood Test: Y N

Other: 

Medications (Check all that apply)

SELECT study participants: please skip this item

1. Cardura® (doxazosin)___
2. Hytrin® (terazosin)___
3. Flomax® (tamsulosin)___
4. Uroxatral® (alfuzosin)___
5. Proscar®/Propecia (finasteride)___
6. Avodart® (dutasteride)___
7. Jalyn (dutasteride/tamsulosin)___
8. Rapaflo (silodosin)___

None of the above___
## Urinary Symptom Assessment

**Over the past month, how often have you...** *(Circle one for each question)*

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Less than 1 time in 5</th>
<th>Less than half the time</th>
<th>Half the time</th>
<th>More than half the time</th>
<th>Almost always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Had the sensation of not emptying your bladder completely after you finish urinating?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Needed to urinate again in less than 2 hours?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Found that you stopped and started again several times when you urinate?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Found it difficult to postpone urination?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Had a weak urinary stream?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Had to push or strain to begin urinating?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>How many times do you typically get up to urinate from the time you go to sleep until you rise in the morning?</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

**Total Urinary Symptom Score:**

At present, are you comfortable with your current urinary situation?............Yes ..... No ........
If you would like and consent to having the results of your PSA blood test and Digital rectal exam sent to your physician, Please complete: (Must Print Clearly)

Physician Name: __________________________________________

Physician Address: _______________________________________

________________________________________________________________________________________________________

Telephone Number: _______________________________________

*** (incomplete/illegible physician address will not be mailed)

SECTION 2 (To be completed by Physician)

Digital Rectal Exam Results:

Normal .................. o BPH .................. 20–30 g. o 30-40 g. o >40 g. o

(2+) (3+) (4+)

Declined/Refused .............. o

**OR**

Digital Rectal Exam Results: (Post Prostate Cancer Treatment)

Normal, expected results after Tx (no further attention required) .............. o

Abnormal, not acceptable results after Tx (further attention required) ....... .... o

**OR**

*Abnormality ............ o (Complete for abnormal DRE only)

Asymmetry ........................................ R > L o L > R o

Induration ...................... Generalized o Localized o (indicate location(s)►)

Nodule(s) ...................... Solitary o Multiple o (indicate location(s)►)

Hardness ...................... Firm o Moderate o Hard o

Physician’s Signature __________________________ Date ______ / ___ / ______

Additional Physician’s notes, if necessary: __________________________________________

______________________________________________________________________________

Section 3: Follow Up (If applicable)

Indication: Abnormal DRE  PSA  PSAV  IPSS

______________________________________________________________________________

R.N. Signature: _____________________________ Date ______ / ___ / _____