# Prostate-specific antigen 1.5: The new screening protocol

Prostate cancer is the leading cause of cancer-related death in American men. Tragically, once the disease is spread beyond the prostate gland, therapies become very limited and survival is poor. Like other cancers, prostate cancer can recur after treatment and will be responsible for more than 26,000 deaths this year. Worldwide prostate cancer related death rate exceeds half a million annually. We know very little about what causes prostate cancer to progress. Early diagnosis of this disease, therefore, can considerably improve long term survival of prostate cancer patients.

Prostate-specific antigen (PSA) is a protein produced by the prostate gland that is secreted into the blood. Often, blood PSA level is elevated above 4 ng/mL in men with prostate cancer. The primary care physician (PCP) is the gate keeper for prostate cancer screening. In fact, they order over 90% of the PSA's in the USA. Unfortunately, there is no straight-forward message for when to refer to a urologist. PCPs may utilize many tests to consider a biopsy such as PSA velocity, age-specific PSA, percent free PSA, PSA density, and PSA cutoffs of 1.0, 1.5, and 2.5. However, a number of benign conditions can also increase a man's PSA level including an infection of the prostate known as prostatitis and an enlargement of the gland known as BPH. As a result, many PCPs are confused about interpreting PSA results. They need a simple message.

Adding to this confusion, the US Preventative Services Task Force (USPTF) in 2012 recommended against annual PSA screening to reduce unnecessary biopsies. However, obtaining a prostate biopsy is necessary to diagnose prostate cancer. This new USPTF recommendation has had a negative side effect; a growing number of men with lethal prostate cancer is now being caught too late. It is clear that a change to the approach of using PSA is needed to safely identify men with lethal prostate cancer. PCPs need precise guidelines for informed decision-making based on PSA results similar to those for other chronic conditions such as mild hypertension, high cholesterol, and prediabetes.

We present an algorithm for PSA screening of men with at least a 10-year life expectancy. Per our algorithm, men with a PSA below 1.5 won't need another drawn for 5 years if they remain urologically asymptomatic. We recommend PCPs refer any man over the age of 50 with either a PSA > 1.5 or with a nodule identified on digital rectal exam to a urologist or consider additional new tests to assess risk. This algorithm is similar to one used when blood sugar levels are higher, where an abnormal result triggers another test such as an A1C hemoglobin. Several companies have developed noninvasive screening tests using patients' blood and urine. Among them, 4KScore, SelectMDx, and Prostate Health Index tests have demonstrated ability to identify patients with lethal cancers in clinical trials. Currently, we prefer SelectMDx to help identify men who should undergo a biopsy it predicts the risk of having lethal cancer. The website, pcmarkers.com, discusses these tests in depth.

We recommend that a biopsy *should not* be performed unless the risk of a lethal tumor is high, and only after a thorough discussion of benefits and risks with the patient. PCPs should emphasize that

the reason for screening is the early identification of potentially lethal disease, and that in most cases low-risk tumors do not require immediate treatment. The greatest benefits of this algorithm is that it could greatly reduce the number of men requiring a biopsy while increasing the screening accuracy for men harboring lethal prostate cancer.

***John Hoenemeyer***
*University of Colorado Health Science Center, Aurora, CO, USA*

## Publication

An Approach Using PSA Levels of 1.5?ng/mL as the Cutoff for Prostate Cancer Screening in Primary Care.
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