

New Blood Test Is Highly Accurate in Identifying Patients at Risk for Prostate Cancer

4Kscore test helps avoid needless biopsies

Cleveland Clinic has recently begun offering a new test that is highly accurate in screening men for prostate cancer, especially for the risk of high-grade cancers that warrant aggressive treatment.

The test, called 4Kscore™, is used if a patient has an elevated prostate specific antigen (PSA) test result.

Most physicians in the United States currently use the PSA blood test as an initial screening tool. Unfortunately, PSA is not specific for prostate cancer, just for prostate issues. Also, PSA levels go up with age as the prostate enlarges, which further increases the test's rate of false positives for cancer, says Andrew Stephenson, MD, Director for the Center of Urologic Oncology at Cleveland Clinic's Glickman Urological & Kidney Institute.

These two factors mean that many men are referred for a prostate biopsy needlessly, and sometimes are diagnosed with unimportant cancers, Dr. Stephenson says.

“Overdiagnosis — the identification of cancers that likely pose no harm to a man’s well-being or longevity — is a big problem with the PSA test,” he says. “The promise of the new test is that it is more specific for prostate cancer and, importantly, it appears to identify patients at risk for high-grade cancers more efficiently than the PSA.”

How the test works

The 4Kscore test combines four prostate-specific kallikrein assay results with clinical information in an algorithm that calculates the individual patient's risk for aggressive prostate cancer.

According to developer OPKO Lab, the test has undergone extensive clinical development and confirmation. The biomarkers it utilizes are based on more than a decade of research involving more than 20,000 men in Europe and the United States. The results were recently replicated in a prospective, blinded clinical study conducted at 26 urology centers across the United States involving 1,012 patients.

When using the 4Kscore test according to the specified threshold OPKO recommends, physicians can reduce the need for prostate biopsy by 30 to 50 percent while still accurately identifying high-grade cancers, Dr. Stephenson says.

“The paradigm that we have used to screen patients for prostate cancer has needed to change for a while,” Dr. Stephenson says. “The U.S. Preventive Service Task Force gave PSA screening a grade of D in 2012 because the harm it brings outweighs the benefits. The 4Kscore test represents a major step in the right direction to improve our prostate cancer screening practices.”

The test's performance is quite good across many patient populations. There is no one demographic that benefits more than others, he says. However, it is more expensive than the PSA test and its cost is not currently covered by insurers. “I am not suggesting the 4K test should substitute for PSA as a screening test,” Dr. Stephenson says. “But using it after an elevated PSA result but before ordering a biopsy will save money and prevent many biopsies.”

Biopsy concerns

Biopsy is worth avoiding when possible, Dr. Stephenson says. It is unpleasant for patients and carries a risk of infection and bleeding. "These risks are low, occurring in 1 to 2 percent of men, but when you consider that 20 to 30 percent of all men undergo a prostate biopsy, that represents an enormous number of patients," he says.

Other prostate cancer screening tests are available, including the Prostate Health Index; however they have not been compared in a head-to-head clinical trial, Dr. Stephenson says.

"Overall, we are getting much more refined about how we screen and diagnose for prostate cancer, and these tests offer great potential to move us in the right direction," he concludes.

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Tags: andrew stephenson, prostate cancer, prostate cancer screening, prostate specific antigen (PSA) test