New Prostate Cancer Tests Could Reduce False Alarms

Cancer Diagnosis: Less Can Be More: Dr. Peter Scardino of Memorial Sloan-Kettering Cancer Center says current prostate cancer screening is painful and imprecise but vastly improving.

By ANDREW POLLACK
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Sophisticated new prostate cancer tests are coming to market that might supplement the unreliable P.S.A. test, potentially saving tens of thousands of men each year from unnecessary biopsies, operations and radiation treatments.

Multimedia

Some of the tests are aimed at reducing the false alarms, and accompanying anxiety, caused by elevated P.S.A. readings. Others, intended for use after a definitive diagnosis, examine the genetic workings of the cancer to distinguish dangerous tumors that need treatment from slow-growing ones that

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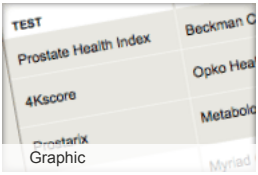

Graphic

New Ways to Assess Prostate Cancer

might be left alone.

The tests could provide a way out of the bitter debate over whether healthy men should be screened for prostate cancer.

The problem with the P.S.A. blood test is that many of the cancers it detects are unlikely to cause harm. But there is no reliable way to identify them. So a large majority of men with positive tests undergo surgery or radiation treatment, and many suffer for years, needlessly, from complications like incontinence and erectile dysfunction.

In late 2011, the United States Preventive Services Task Force, a government advisory body, provoked a furor by recommending against screening, saying that far more men were harmed by unnecessary biopsies and treatments than were saved from dying of cancer.

But if new tests can better determine risk, screening could become more useful.

“It’s not that screening doesn’t work; it’s that we haven’t done a great job of targeting treatments for the tumors that need it,” said Dr. Matthew R. Cooperberg, an assistant professor of urology at the University of California, San Francisco who has been a consultant to some of the testing companies.

Reducing unnecessary treatments could also reduce the $12 billion in estimated annual spending related to prostate cancer. Test developers hope that such savings will make their tests cost-effective, even at prices that will exceed $3,000 in some cases.

More than a dozen companies have introduced tests recently or are planning to do so in the near future. Rather than looking at a single protein like P.S.A., which stands for prostate-specific antigen, many of these tests use advanced techniques to measure multiple genes or other so-called molecular markers.

“It’s the cancer for the next 18 to 24 months that will be transformed by molecular markers,” said Dr. Doug Dolginow, chief executive of GenomeDx Biosciences, a start-up planning to introduce a test later this year.

Experts caution that it is too early to tell how well most of

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Researchers at GenomeDx Biosciences perform genomic analysis. The company plans to market a test this year that would be used after surgery to help determine whether a patient should receive additional treatment.

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Researchers Elai Davicioni, right, and Jenne Hansentake analyze samples from a prostate tumor in GenomeDx’s lab in San Diego.

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Doug Dolginow, right, chief executive of GenomeDx Biosciences, with Elai Davicioni, president and chief scientific officer.

the tests will perform and whether they will make a difference. Although the tests are intended to help men make treatment decisions, the onslaught of so many could cause more confusion.

"It's a little tricky to find out which one applies to you and whether it will be paid for by insurance," said Jan Manarite, who runs the telephone help line for the Prostate Cancer Research Institute, a patient education organization.

Prostate cancer specialists say screening has declined since the task force recommended against it, but millions of men in the United States still get regular blood tests to measure P.S.A. As many as a million have biopsies each year, with about 240,000 prostate cancer cases diagnosed and 28,000 deaths from the disease.

The biggest battle among test developers could be between Genomic Health and Myriad Genetics, which are moving into the prostate cancer field after successes in breast cancer testing.

Myriad is known for its test for genetic mutations that raise a woman's risk of getting breast cancer. Genomic Health's Oncotype DX test helps determine if a woman should receive chemotherapy.

Both companies have developed prostate tests analogous to Oncotype DX. They analyze gene activity levels in the tumor sample obtained by biopsy to gauge how aggressive the cancer is, helping doctors and patients decide whether to treat it. The companies say their tests provide better information than the Gleason score, the main tool now used to assess tumor aggressiveness, which is based on how cells look under a microscope.

One study of Myriad's test looked at stored biopsy samples from 349 British men who were found to have prostate cancer from 1990 to 1996 and did not receive immediate treatment.

About 19 percent of the men with the lowest risk scores on Myriad's test died from prostate cancer within 10 years, compared with 75 percent of the men with the highest risk scores, according to results published last year in the British Journal of Cancer.

Still, some prostate cancer specialists say the test, which is called Prolaris and went on sale last year, has not been adequately validated, and sales have been very low. Noridian, the Medicare contractor for Utah, where Myriad is based, said it would not pay for the $3,400 test.

Genomic Health says it plans to start selling its test, the Genomic Prostate Score, after releasing supporting data at the American Urological Association's annual meeting in May.

Insurers might be reluctant to pay for the new tests without evidence that men will trust the results enough to forgo treatment if so indicated. The tests still leave some uncertainty, and many men do not want to live with cancer, no matter how slight some test says the risk is.

"We already know from conventional information that there are a group of men who are very unlikely to have progression, but they still get treated," said Dr. Lee N. Newcomer, senior vice president for oncology at UnitedHealthcare.

Angel Vasquez, for example, resisted when his urologist told him that he could forgo treatment based on his low Gleason score and P.S.A. levels.

"I said, 'No, my philosophy is if there is something in my body that is not supposed to be there, I want it to come out,' " said Mr. Vasquez, 67, of Matthews, N.C.

The doctor ordered Myriad's Prolaris test. Rather than justifying a decision to watch and wait, the test showed the tumor to be more aggressive than thought, a finding later confirmed after Mr. Vasquez had surgery.

"Had I left it alone, it would have really progressed," he said.

Some experts say that even if the new tests are not perfect, they are better than what is available now.

"Even if we can only convince 15 to 20 percent of men that we have enough confidence that they don't need to be treated, that will be a big step forward," said Dr. Eric A. Klein of the Cleveland Clinic, who has worked with Genomic Health.

Another company, Bostwick Laboratories, already sells a tumor aggressiveness test called ProstaVysion, and Metamark Genetics is developing its own.

GenomeDx is focusing on a test that would be used after surgery to help determine whether additional treatment with radiation or drugs would be useful. Danaher already sells such a test.

Hologic, MDxHealth and Mitomics sell tests that they say can reduce the number of unnecessary second biopsies, which are often done when a first biopsy is negative but P.S.A. levels remain high.

Opko Health, Beckman Coulter and Metabolon are developing tests that would be used in conjunction with P.S.A. screening. Because P.S.A. levels can be elevated for reasons other than cancer, as many as three-quarters of biopsies do not find cancer — and the biopsies can cause pain and infections.

One published study showed that Opko's test could have reduced unnecessary biopsies by about 50 percent, though it would have missed 12 percent of high-grade cancers.

Yet another test could come from the discovery by researchers at the University of Michigan that a particular fusion of two genes is found in half of prostate cancers, and only in prostate cancer.

"You'd still miss 50 percent of the disease, but at least you know if you have it you have prostate cancer," said Dr. Arul M. Chinnaiyan, a professor of urology and pathology. He said a urine test was being developed that combines the gene fusion with PCA3, another marker.

Some experts say unnecessary procedures can be reduced simply by using the P.S.A. test less frequently, and also by improving imaging. The new tests are “singles and doubles at best,” said Dr. William J. Catalona, director of the prostate program at Northwestern University, who helped bring the P.S.A. test to market in the 1990s. But, Dr. Catalona said, this is only the start. “This field is moving kind of like cellphones,” he said.

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