The PSA Test: Beating The Odds Against Prostate Cancer

Roswell Park Cancer Institute

Just decades ago, having prostate cancer was like a death sentence because diagnoses typically occurred in the late stages of the disease. But thanks to the prostatespecific antigen test developed at Roswell Park Cancer Institute, thousands have received early diagnoses and treatment.

When Stanley Inhorn, M.D., visited his doctor for a routine checkup in 1992, he was in for an ominous surprise.

"My wife had encouraged me to get a PSA test during my visit to the doctor. I was 64 at the time and had not had one prior to that," says the former professor of pathology and preventive medicine at the University of Wisconsin-Madison's Medical School. "In retrospect, I'm glad she did."

The results of Inhorn's prostate-specific antigen, or PSA, test indicated he might have prostate cancer. Further follow-up tests and a biopsy confirmed that was, in fact, the case. He sought treatment and has been cancer-free ever since. Now retired, he is actively involved in public health issues including cancer prevention, and is one of more than 1.8

million prostate cancer survivors leading fruitful lives in the United States.

Prostate cancer is second to lung cancer as the leading cause of cancer death in American men. Roughly one out of six men will be diagnosed with prostate cancer during his lifetime.

> *In 2005 alone, an estimated 232,090 new cases of prostate cancer were diagnosed in the United States, and more than 30,000 Americans die from the disease every year.*

The good news is that over the past two decades, the survival rate for prostate cancer has increased from 67 percent to 97 percent. And one of the most powerful weapons against prostate cancer is the PSA test.

"The PSA test absolutely revolutionized the way we approach prostate cancer diagnosis," says Donald Trump, M.D., senior vice president for Clinical Research and chair of the Department of Medicine at the Roswell Park Cancer Institute in Buffalo, N.Y., where the initial research on the PSA test was conducted.

The PSA test is used to detect prostate cancer long before the symptoms appear, which typically occurs in the more advanced stages of the disease — often when it is considered too late for treatment.

"Before the PSA test came along, being diagnosed with prostate cancer was almost like a death sentence," says Richard Matner, Ph.D., director of technology transfer and commercial development at the Roswell Park Cancer Institute. "But the PSA gives prostate cancer patients an 'advanced warning' so they can consider various treatment options before the cancer spreads."

Administered to millions each year, this simple blood test has practically become routine for American men in their 50s and older. Besides being used for early detection, it is a valuable tool in monitoring the efficacy of treatments for those already diagnosed with prostate cancer, and it is an effective predictor of the disease's recurrence.

How the PSA Test Works

Prostate-specific antigen is a protein produced by the walnut-sized prostate gland surrounding the urethra in men. When prostate cancer or benign conditions occur, PSA levels increase — so higher PSA levels are used as a marker to detect the disease. The PSA test measures the level of PSA in the blood. Once a patient's blood is drawn, PSA levels are measured in the laboratory, indicating whether or not he might potentially have prostate cancer.

Though PSA levels alone do not offer enough data to distinguish between benign or cancerous prostate conditions, physicians and their patients use PSA test results to determine the next steps in checking for other signs of cancer.

Age is a major risk factor for prostate cancer. More than 70 percent of all prostate cancers are diagnosed in men older than 65. Race is a factor as well; prostate cancer is twice as common among African-American men as it is among Caucasian men. The American Cancer Society recommends that doctors offer the PSA blood test and the digital rectal examination yearly, beginning at age 50 for men who do not have any major medical problems, and beginning at age 45 for men at high risk.

An Ambitious Research Effort

The PSA test's origins can be traced to the pioneering work of researchers led by T. Ming Chu, Ph.D., at the Roswell Park Cancer Institute. In 1979, Chu and Ming C. Wang, Ph.D., Luis A. Valenzuela and Gerald P. Murphy, M.D., D.Sc., reported the discovery and purification of the PSA. Working with Lawrence D. Papsidero, Ph.D., the following year, Chu demonstrated the presence of PSA in the blood of prostate cancer patients. Together with Manabu Kuriyama, M.D., Chu developed a test to detect PSA in 1980, and in 1981 Chu worked with Murphy to further evaluate and refine the clinical value of PSA. The U.S. Patent and Trademark Office awarded Chu, Wang and Papsidero a patent for the PSA test in 1984.

Research Corporation Technologies Inc., based in Tucson, Ariz., acquired patenting and licensing rights to Chu's PSA test technology, and licensed it on a nonexclusive basis to Hybritech Inc., a pioneering San Diego biotech company that is now part of Beckman Coulter in Fullerton, Calif. Hybritech developed the first commercially viable PSA test, approved by the U.S. Food and Drug Administration in 1986. This test was approved only for monitoring the progress of prostate cancer patients undergoing treatment. In 1994 the FDA approved the PSA test for use as a screening tool for the general public.

The PSA Test's Impact and Benefits

Since the introduction of the PSA test as a monitoring and screening tool, prostate cancer survival rates have dramatically increased. In one study conducted in 1991, 32 percent of the prostate cancers identified by biopsies would have been missed if the PSA test had not been used as a screening tool. A 2005 study indicated men who receive yearly PSA tests are three times less likely to die from prostate cancer compared to those who don't have annual screenings.

> *"There is no doubt that thousands of men would not be alive today if the PSA test had not come along," Trump says.*

Though Trump and others point out there isn't enough hard data available to scientifically prove that PSA tests lower prostate cancer mortality rates, those studies are now under way. Some in the medical field harbor reservations about false positives and negatives associated with the test, but proponents point to the PSA test's role in thousands of early diagnoses — crucial in helping prostate cancer patients beat the odds against the disease through successful treatment. Additionally, the PSA test continues to be refined and enhanced as a result of ongoing research.

Economically, the PSA test has had a significant impact as well. "Overall, 20 companies ended up licensing the PSA test technology from RCT, which led to significant job creation and generated millions in sales," says David A. Wiersma, Ph.D., a senior associate at Research Corporation Technologies. "The PSA test remains the biggest-selling commercial diagnostic test of its kind," Wiersma adds.

What began as an ambitious research effort in Roswell Park Cancer Institute's laboratories more than a quarter century ago clearly has become one of technology transfer's greatest success stories.

Just ask Stan Inhorn, who soberly notes, “I might not be here today if I hadn’t taken that PSA test.”

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