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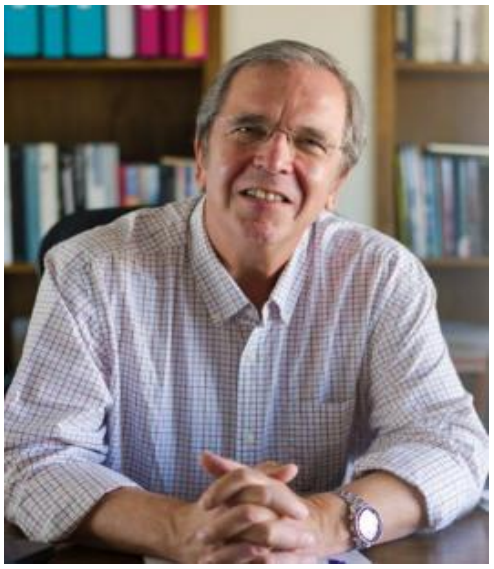
Reporter Backgrounder:
Oncotype DX® For Prostate Cancer

Addressing the Overtreatment of Prostate Cancer

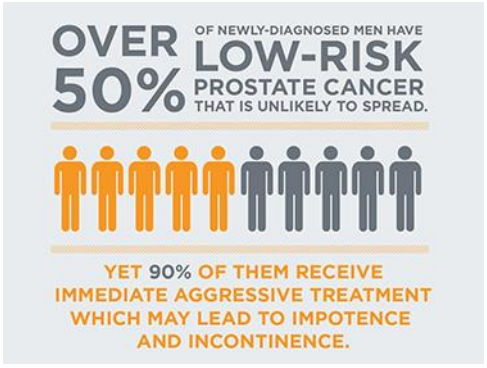


More than 240,000 men are diagnosed with prostate cancer each year in the United States and more than half are estimated to have clinically low- and intermediate-risk disease. Most of these men receive immediate aggressive treatment such as surgery to remove the prostate or radiation, despite the cost, risk of serious side effects such as incontinence and impotence and minimal benefit. This recognized overtreatment of early-stage prostate cancer is due to the inability of traditional measures, including tumor stage, PSA level, and Gleason score, to fully determine whether a man has low-risk prostate cancer that can be managed with active surveillance, or whether he has aggressive prostate cancer that should be treated immediately with surgery or radiation therapy.

Active Surveillance

Under active surveillance, patients have regular check-ups and periodic PSA blood tests, clinical exams and potential biopsies to closely monitor for signs of prostate cancer progression without removing the prostate.

What is the Oncotype DX Genomic Prostate Score (GPS)?



Developed in collaboration with the University of California, San Francisco (UCSF) and Cleveland Clinic, the Oncotype DX GPS helps physicians and their patients confidently choose the most appropriate treatment in each individual case. The first-of-its-kind, multi-gene test has been validated to determine the aggressiveness of each man's individual tumor, thereby providing the opportunity for low-risk patients to avoid invasive treatments such as prostatectomy or radiation – and their side effects – while identifying men who need immediate invasive treatment.

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How Does the Test Work?

The Oncotype DX GPS test analyzes 17 genes across four biological pathways from tumor tissue removed during the biopsy to provide an individual score that, in combination with other clinical factors, helps clarify a man's risk.

What Does Research Say?

With 14 studies that have included more than 2,000 patients, the Oncotype DX GPS has been specifically developed and validated to assess the aggressiveness of prostate cancer prior to treatment intervention. A positive clinical validation study led by UCSF showed that the GPS test strongly predicted the likelihood of aggressive disease at the time of the biopsy, offering information beyond currently available clinical factors and potentially tripling the number of patients who can confidently choose active surveillance and avoid side effects of invasive treatments. This study was published in European Urology.

A second clinical validation study conducted in collaboration with the Center for Prostate Disease Research and published in European Urology, reconfirmed the biopsy-based GPS test as a predictor of adverse pathology at surgery, and validated the test as a strong independent predictor of PSA following surgery. This study also demonstrated that the Oncotype DX GPS was similarly predictive of outcomes in Caucasian and African-American men.

"Data from actual patient charts add an important real-life perspective on the value of our test."

- Phil Febbo, M.D., Chief Medical Officer

Urology Practice, an official journal of the American Urological Association (AUA), published positive results from two decision impact studies demonstrating use of the Oncotype DX GPS in treatment planning resulted in increased recommendations and acceptance of active surveillance as initial management of prostate cancer in low- and low-intermediate risk patients.

Is It Covered by Insurance?

Palmetto GBA, a Medicare Administrative Contractor (MAC) that assesses molecular diagnostic technologies, has initiated reimbursement coverage of the Oncotype DX GPS for qualified Medicare patients throughout the United States.