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Two Big Studies Tackle Debate On Prostate Test

By [KEITH J. WINSTEIN](#)

Interim results from two of the most rigorous studies to date on prostate-cancer screening have failed to bring any clarity to one of the most contentious issues in men's health.

The results, which come after 15 years of study of 240,000 men, don't resolve a longstanding argument about whether all older men should be regularly screened. One study, conducted in Europe, has so far found modest screening benefits in lowering death rates, but with the high cost of side effects. The other, in the U.S., hasn't found any benefit.

When the dust settles, doctors say screening guidance will likely stay the same: African-Americans and men with a family history of prostate cancer should lean more toward regular screening; others should weigh their own risk factors and the possible benefits of screening with their doctors.

Cancer of the prostate, which is a gland that makes semen, is the No. 2 cancer killer of men -- it will kill about 28,700 U.S. men this year. A blood test for a chemical called prostate-specific antigen, or PSA, can detect the cancer, and most men over 50 in the U.S. have been screened.

But whether PSA testing, introduced in 1987 to monitor men who already had prostate cancer, saves lives when used as a screening tool, has long been controversial. Most prostate cancers grow slowly and never kill, and treatment options -- which include surgery, radiation and hormone-modification therapy -- carry side effects such as sexual impotence and incontinence.

Wednesday, European and U.S. health authorities released interim looks at two major studies of prostate-cancer screening that began in 1993. The studies enrolled a total of 240,000 men, with about half assigned to be regularly screened for PSA, and then tracked cancer diagnoses and deaths. The results were published online by the New England Journal of Medicine and presented at a urological conference in Stockholm.

U.S. authorities said they decided to release the data early because of the concern that too many men are being treated and suffering side effects without receiving a benefit. Prostate cancers usually progress so slowly that patients die for other reasons first. So a practice of routine screening and treatment of detected cancers can lead to unnecessary side effects, said Christine Berg, a National Cancer Institute official who supervised the U.S. study. "Many people, when they're hit with the diagnosis of cancer, think that they're going to die tomorrow," Dr. Berg said.

After seven to 10 years of follow-up, the U.S. study, run by the National Cancer Institute and including 77,000 men aged 55 to 74, hasn't found any benefit from routine screening. The trial compared a group of men who were

encouraged to be regularly screened for PSA and with a rectal examination -- 85% were actually screened -- against a control group that received prevailing medical practices, or about a 50% rate of screening. Men in the screening group were 22% more likely to have a cancer detected, and positive results usually lead to treatment. But between the two groups, the rates of prostate-cancer deaths were in a statistical tie: In each group, roughly 200 deaths per million men each year.

Overall, men in the U.S. "have a 3% or less risk of dying from prostate cancer, but a 16% or 17% chance of being diagnosed with prostate cancer in their lifetime," Dr. Berg said. Wednesday's interim release of data didn't include information on the rate of side effects or "quality of life," but those will be included in a later analysis in coming years, she said.

"You need to talk with your health-care provider about your own individual risk profile, based on your age, your family history, and your tolerance for risk and side effects," Dr. Berg said. African-Americans and those with a family history of prostate cancer have a higher average risk.

The second article, an interim look at seven European studies that together enrolled 162,243 men, age 55 to 69, did find a modest benefit from routine screening after about nine years of follow-up. Men in the screening group had an annual death rate from prostate cancer of 350 deaths per million men, compared with 410 deaths per million men in the control group.

But that benefit came at a cost: By the European data, saving one life from prostate cancer would require treatment of 48 men. In other words, 47 men would be unnecessarily treated -- many suffering urinary incontinence or sexual problems -- for every life saved.

"In the past, it was a Russian roulette, because we didn't know the risks and the benefits," said Fritz Schröder, a Dutch doctor who led the European analysis. "We know now that screening does decrease prostate-cancer mortality," he said. The study's final analysis will be published in four years, Dr. Schröder said.

The two studies aren't likely to resolve the disagreement about routine screening, which is popular in the U.S. but not in Europe. "Everybody recommends against mass screening, and the irony is, screening is very common in the U.S.," said Otis Brawley, an Atlanta oncologist and chief medical officer of the American Cancer Society.

"There is a disconnect in the American public, and maybe these two trials ... will help legitimize the question so people will stop just doing screening and actually think about it and make a conscious decision," Dr. Brawley said.

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