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Test to Help Determine If Ovarian Masses Are Cancer

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By L A U R A J O H A N N E S

Doctors and hospitals are getting a new test that many think will help fight ovarian cancer, one of the deadliest cancers, by helping them to more quickly distinguish cancerous from benign growths.

The test, which is called OVA1 and will be available for general use Tuesday, was shown to correctly flag 92% of cancers, when used along with radiological imaging and a standard patient work-up, in a study of 27 hospitals, doctors' offices and clinics. Physicians using their usual detection methods but not OVA1 had previously found 72% of the cancers.

Deadly

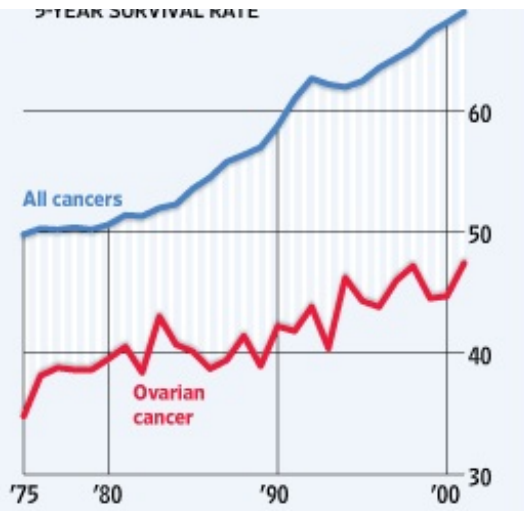
5-YEAR SURVIVAL RATE

70%

"It is an amazing move forward," says Cara

Cancer

The five-year survival rates for ovarian cancer have lagged behind the overall cancer survival rate:



Source: National Cancer Institute

Tenenbaum, vice president of policy for the Ovarian Cancer National Alliance, a nonprofit patient advocacy group.

The test, though, has a serious downside: It generates a lot of false positives. Of the women flagged as likely having cancer, 64% didn't, as determined by biopsies done during surgery.

False positives might prompt, in addition to the likely emotional suffering, women to make an out-of-town trip to have surgery under a specialist's care when it could have been done at a local hospital. The trial funded by Vermillion Inc., of Fremont, Calif., which developed the test, found that physicians' current methods, which generally included another blood test, an exam and imaging, had a false-alarm rate of only 40%.

Ovarian cancer, the ninth most common cancer among women, has a dismal 47% survival rate, up from 38% in the mid-to-late 1970s. During that time, the overall five-year survival rate from cancer improved more dramatically: 68% for people diagnosed in 2001, up from 50%. An estimated 5% to 10% of women will undergo surgery for ovarian masses during their lifetimes, many of which will be benign.

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Cancer Clues

A new test measures five proteins that increase or decrease in your blood if you have ovarian cancer:

PROTEIN	Function	LIKELY CHANGE IF YOU HAVE CANCER
Apolipoprotein A1	Cholesterol Transport	DOWN
Beta 2 microglobulin	The body's immune response	UP
CA125	Released by tumor cells	UP
Prealbumin	Hormone and vitamin transport	DOWN
Transferrin	Iron transport	DOWN

Source: Vermillion Inc.

Much of the problem is that ovarian cancer is often detected too late. Not everyone has symptoms, and the classic ones—bloating, pelvic pain, difficulty eating and urinary frequency, are easily confused with other maladies.

OVA1 won't help find cancers earlier, but it might help get women faster to doctors best trained to treat the cancer. Two-thirds of ovarian cancers are first operated on by general gynecologists or surgeons, even though outcomes are better when the job is done by specialists called gynecologic oncologists, according to scientific literature.

Gynecologic oncologists have training to remove cancer that has spread beyond the original tumor, says Carolyn Muller, a University of New Mexico physician and a spokeswoman for the Society of Gynecologic Oncologists. They are also trained to "stage" the disease, or assess its severity, she says.

"Patients who get more thorough surgery or more thorough staging up-front will get more appropriate treatment, and therefore will have a better chance of living longer," says Robert C. Bast Jr., a medical oncologist at the University of Texas M.D. Anderson Center. Dr. Bast, co-inventor of a blood test called CA125, currently cleared by the FDA for monitoring ovarian-cancer patients, is a paid member of Vermillion's scientific advisory board.

Knowing cancer is present before surgery also prevents some patients from having to take a second trip to the operating room for a specialist to finish the job. Cindy Hastings, a 52-year-old nurse from Fremont, Calif., had a hysterectomy Sept. 3 to remove an ovarian mass her local gynecologist thought was benign. When the mass turned out to be cancer, Ms. Hastings had a



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second surgery six days later by a gynecologic oncologist, who removed 42 lymph nodes. She says the double surgery, including two anesthetics, was stressful on her body. After the second surgery, she says she was so bloated, "I looked four months pregnant." She adds, "I was a couple of months too early" to benefit from OVA1.

The \$650 test, which was cleared by the U.S. Food and Drug Administration in September, will be sold through [Quest Diagnostics Inc.](#), the nation's largest medical-testing lab.

Tests for ovarian cancer have proved challenging to develop and gain FDA approval because it is difficult to prove a screening test is accurate. Laboratory Corp. of America in 2008 withdrew its OvaSure screen, designed to find cancer in high-risk women, from the market after the FDA and many physicians questioned its accuracy. Correlologic Systems Inc., Germantown, Md., was originally hoping to develop a test for finding cancer in high-risk women, but now is aiming for a more modest goal of a test with a purpose similar to the OVA1. Arrayit Corp., Sunnyvale, Calif., says it is working on a screening test, but it isn't clear yet if it will pass muster with the FDA.

Two other ovarian-cancer tests cleared by the FDA are CA125, widely available since 1987, and HE4, which hit the market in 2008. The tests, which involve single proteins that are markers for the cancer, are cleared only for use in monitoring patients who have been treated for the cancer. CA125 is widely used off label to determine if masses are cancerous prior to surgery, but it misses many cancers, scientists say.

OVA1 is the first multi-protein ovarian-cancer test cleared by the FDA. The test combines the CA125 test with assays for four other proteins, levels of which are likely to either rise or fall as the body responds to cancer. Based on the results, patients are assigned a score from 0 to 10; a score of 4.4 or higher in post-menopausal women, and 5 or higher in pre-menopausal women, indicates an elevated risk of cancer.

Full results of the OVA1 trial, run by the University of Kentucky Medical Center and funded by Vermillion, will be presented March 17 at the Society of Gynecologic Oncologists. According to study data outlined in the FDA-approved package insert for OVA1, the study found the test plus a standard patient work-up by general gynecologists, including ultrasound or CT scans, correctly predicted 92% of the cancers prior to surgery. The same doctors found only 72% of the cancers using the standard work-up, which in most cases, included a CA125 test. When both the OVA1 test and the doctors' assessments predicted masses were benign, the women were cancer-free 93% of the time.




A rival test being developed by Japan's Fujirebio Inc., called Risk of Malignancy Algorithm, or

ROMA, was shown in a trial published last year to detect 89% of cancers pre-surgery with only a 25% false-positive rate. Fujirebio is conducting more research and plans to apply for FDA clearance this fall. The test involves both the CA125 and HE4 markers.

So far no major insurers have told Vermillion that they will cover the cost of OVA1. Neither Aetna Inc. nor Cigna Corp. currently cover the test, but both say they may reconsider once further evidence becomes available. Wellpoint Inc. says it is reviewing the matter and in the meantime will decide whether to cover on a case-by-case basis. Wellpoint Inc. says it is reviewing the matter and in the meantime will decide whether to cover on a case-by-case basis.

Write to Laura Johannes at laura.johannes@wsj.com

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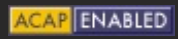
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