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Cepheid Inc. of Sunnyvale to help defeat dangerous 'superbug'

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Cepheid Inc. first made its name with anthrax-detection tests to guard the nation's post offices from bioterrorism attacks back in 2001.

Now, the Sunnyvale company's gene-based testing system is becoming part of an escalating nationwide defense against the deadly "superbug" called MRSA, which is often innocently spread by well-meaning health care workers.

Cepheid won Food and Drug Administration approval in April for its test for a life-threatening, antibiotic-resistant form of the common staph bacterium, a strain that now kills more people in the United States each year than the AIDS virus. The microbe, methicillin-resistant Staphylococcus aureus, or MRSA, can cause stubborn skin eruptions, pneumonia and bloodstream infections that can be fatal unless an effective antibiotic is given in time. Methicillin, penicillin and related drugs are powerless against the germ, so doctors must use alternative antibiotics such as vancomycin.

Just how widespread MRSA has become was revealed this month when scientists at the Centers for Disease Control and Prevention published results of a large-scale surveillance study based on samplings in the Bay Area and other regions. The researchers estimated that 94,360 cases of invasive MRSA infection occurred in the United States in 2005, resulting in 18,650 deaths.

Most testing for the aggressive staph germ takes 24 hours or longer, because technicians must wait for the microbe sample from a patient's nasal swab to grow in a culture dish. Cepheid reduced that time to 72 minutes with a test that recognizes the DNA signature of the resistant germ, said Cepheid Chief Executive Officer John Bishop. Patients who test positive can start treatment sooner with an antibiotic that still works against the bacteria, he said. The MRSA test is processed by the company's GeneXpert system, the automated analyzer also used with its anthrax test.

The scale of the demand for Cepheid's MRSA tests will depend on the outcome of an active debate among hospital and public health officials over the best methods to protect people from the dangerous microbe. Some experts say a significant portion of patients admitted to a hospital should have their noses swabbed

for testing, said Dr. John Jernigan, a CDC medical epidemiologist and MRSA expert.

The germ, which spreads easily by contact with another person's skin or with contaminated objects such as bedrails and sheets, is a serious hazard for hospital patients. It can infiltrate the body through surgical wounds, catheters and other means.

The majority of MRSA cases originate in hospitals and health care facilities among patients with weakened immune systems and other risk factors. But the germ also can be brought into the hospital from outside. The recent CDC study found a significant incidence of MRSA exposure among healthy people who congregate in schools and other community centers.

Even so, some health care officials say mass testing at the point of hospital admission is not necessary if strict sterile procedures are used with all patients, Jernigan said. That includes old-fashioned measures such as frequent hand-washing and gown changes by health care staff.

Cepheid testing systems are in use under two contracts with the Department of Veterans Affairs, which just announced stringent new MRSA screening requirements at all 153 of its hospitals. All patients admitted to intensive-care units and other high-risk wards are tested, although the department does not mandate the use of rapid diagnostic systems such as Cepheid's.

In addition to its MRSA test, Cepheid sells two other clinical infectious disease tests for the GeneXpert system, and plans to introduce many more, Bishop said. But he said alarms over MRSA are already increasing demand for the instruments, and the company's manufacturing units are gearing up to meet it.

"MRSA will be the biggest driver of sales in the near term," he said. Cepheid's smallest GeneXpert analyzer costs \$27,000. The price per MRSA test is \$42.

Caris & Co. analyst Zarak Khurshid estimates that Cepheid could reap \$21 million in sales of the analyzer systems and nearly \$33 million in MRSA test components in 2008.

"The business is growing extremely fast and could outstrip those estimates," Khurshid said. Caris & Co. makes a market in Cepheid shares. In 2006, Cepheid's biothreat detection products contributed 58 percent of the company's \$87.3 million in revenue.

The life-threatening form of the common "staph" bacterium is part of a larger class of drug-resistant infections created by the widespread use and overuse of antibiotics.

When such drugs are first introduced, they can stop the growth of nearly all the individual microbes causing an infection. But the antibiotic also gives a survival edge to mutated forms of the germ that can thrive despite the treatment. Over time, the antibiotic-resistant strains make up a larger and larger percentage of the bacterial population.

In 1974, methicillin-resistant *Staphylococcus aureus* infections accounted for only 2 percent of total staph infections, the CDC estimates. In 1995, that figure rose to 22 percent. Now, MRSA account for more than 60 percent of staph infections.

It's natural to ask why doctors don't use alternative antibiotics such as vancomycin against all staph infections, given that patients with the resistant germ can worsen or die if their treatment begins with a drug that doesn't work, said Dr. Paul Akins, director of the neuro intensive-care unit at Kaiser Permanente in Sacramento.

But he said blanket use of alternative antibiotics would foster the development of germs resistant to those drugs as well, leaving doctors with fewer remaining weapons against MRSA. Vancomycin resistance is already showing up in staph cultures.

Several companies are trying to create a new generation of antibiotics against the microbe, including Theravance of South San Francisco. Last week, Theravance said the FDA has asked for further information about the clinical testing and manufacturing of its experimental antibiotic telavancin. The agency indicated it might approve the drug after reviewing the additional data.

Akins has been studying methods to reduce MRSA infections in his intensive-care unit, including screening all patients who are admitted to the unit.

He uses the old culture plate test, but he was intrigued by a description of Cepheid's rapid test. "It could be cost-effective," he said. Complications of MRSA can be pricey and dangerous to correct, he said.

On the other hand, the older lab tests have some advantages when it comes to choosing the right alternative antibiotic for each MRSA-infected patient, he said.

The culture dish includes small pieces of paper, each soaked in one of 10 or 15 different antibiotics. The microbes grow all over the papers containing drugs that won't work for that patient, he said. Akins chooses a drug that stops the microbe colony at the edge of the paper.

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