

Quicker, Simpler Tests Sought for MRSA Screening

BY BETSY BATES
Los Angeles Bureau

Researchers at the Mayo Clinic and elsewhere are racing to develop rapid-detection tests for *Staphylococcus aureus*, both to better tailor appropriate antibiotic prescribing and to halt the galloping spread of methicillin-resistant strains of the bacteria.

The race for quicker, easier, better rapid detection tests has been intense, said Betsy McCaughey, Ph.D., director of the New York City-based nonprofit Committee to Reduce Infection Deaths.

"There are many companies now developing rapid tests. I've visited at least half a dozen," she said in an interview.

Among the contenders are Innovative Biosensors Inc. in College Park, Md., which is using light-based technology de-



These tests would be useful when patients have serious disorders that could be exacerbated by a delay in treatment.

DR. PITTELKOW

veloped at the Massachusetts Institute of Technology; Cepheid, a Sunnyvale, Calif.-based company about to introduce another genetic-based rapid test; and 3M, which has "waded deep into this territory," Dr. McCaughey said.

Progress has been keenest in identifying colonized patients prior to or during hospitalization to help reduce the spread of resistant bacteria.

At the University of Maryland Medical Center in Baltimore, for example, patients considered at risk for methicillin-resistant *S. aureus* (MRSA) can be screened in 2 hours with a polymerase chain reaction (PCR) DNA test developed by Becton, Dickinson & Co., rather than waiting 24-48 hours to get an answer by culturing for the bacteria.

All intensive care unit patients are being screened at admission, on a weekly basis, and on discharge so that infected patients can be identified and treated with appropriate isolation and contact precautions, said Richard Venezia, Ph.D., professor of pathology and director of clinical microbiology at the university.

Efforts to further screen patients with risk factors—a previous hospital admission or recent use of antibiotics, for example—are "almost in full swing," he said in an interview.

"This is the first of a generation of tests that are going to be using 'within-the-tube' closed systems," based on either DNA or immunology, that represent a major technological advance in the way risky bacteria are identified, he said.

The tests do not require the level of training or sophisticated precautions against cross-contamination that were necessary with previous PCR procedures developed in research laboratories; neither do they require complex interpretation, because they provide a "yes/no/repeat the test" type answer.

The new tests are currently confined to hospital or community laboratories, but Dr. Venezia said that they will almost certainly be available for bedside or community office practices within 5 years.

At the Mayo Clinic in Rochester, Minn., two swab-based PCR tests are being developed, one to signal the presence of *S. aureus* and the other to identify MRSA, Dr. Mark Pittelkow, professor of dermatology, said in an interview.

The Mayo tests are expected to receive

FDA approval in early 2007 and to be available by midyear.

Although the tests are envisioned as entrants into the hospital infection prevention market, Dr. Pittelkow emphasized their usefulness for clinicians in private practice as well, particularly when their patients have serious disorders that could be exacerbated by a delay in treating MRSA.

"We're seeing a number of [skin] infections occurring as comorbidities or ag-

gravating skin conditions." In the past, many physicians empirically treated patients using antibiotics that could put patients at risk of resistance to a different bug causing a bigger problem, he said.

From minor skin conditions such as impetigo to serious keratodermas, pemphigus, and blistering disorders, *S. aureus* is rapidly overcoming streptococcus as the bacteria of concern, Dr. Pittelkow said.

The Mayo tests, to be marketed by



Roche Pharmaceuticals, use a specially designed swab that does not wick samples in the same way as a cotton-tipped swab. For now, it still requires laboratory technicians to transfer material from the applicator to a plate for analysis, but the technology is heading toward a self-contained swab similar to those used for rapid strep tests in physicians' offices.

The Becton, Dickinson & Co. test, which has been available since early 2006, is approved only for detecting colonization, not to guide antibiotic choices in individual patients. It requires laboratories to make an initial investment of more than \$20,000 for a real-time PCR cyler, plus

\$20-\$30 for each test performed. The equipment, however, can be used to perform other cutting-edge tests for detection of influenza, respiratory syncytial virus, and vancomycin-resistant enterococci, and it potentially saves hospitals the substantial cost of treating MRSA infections, said Dr. Venezia.

Rapid, practical, easy-to-perform tests for *S. aureus* will become even more necessary for hospitals, because the Centers for Medicare and Medicaid Services has proposed that Medicare diagnosis-related group reimbursements for nosocomial infections be stopped.

Pressure is already on hospitals to re-

duce transmission of infections, but the advent of such restrictions on payments for hospital-acquired illnesses might lead some institutions to universally test patients on admission and throughout their stays. Treatment of an MRSA infection can run as much as \$36,000, said Barbara Kalavik, director of worldwide public relations for Becton, Dickinson & Co.

Just who pays for the tests is still a matter of contention.

When a physician orders a test to pinpoint the best antibiotic to treat a patient, the cost can be charged to the patient or insurance,

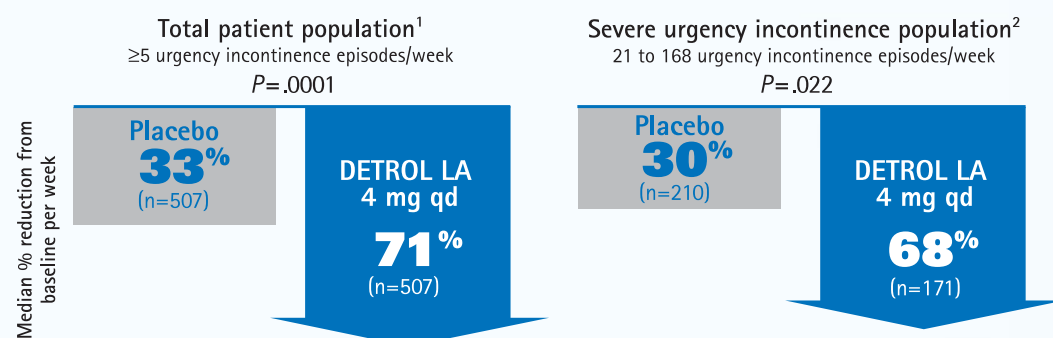
Who will bear the cost of screening hos-

pital patients is less clear, said Ms. Kalavik.

"Most hospitals absorb the cost of these programs," she said, but "starting Jan. 1, 2007, new CPT codes have been instituted that allow for hospitals to be reimbursed approximately \$49 for screening outpatients to see if they are positive for MRSA."

From a research point of view, widespread use of tests to detect *S. aureus* and MRSA could better characterize the incidence of infections and their hosts. For example, "there may be three to four body surface areas more likely to be harboring *S. aureus*, along with nasal carriage," Dr. Pittelkow said. ■

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Van Kerrebroeck et al. *Urology*. 2001;57:414-421.¹
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Landis et al. *J Urol*. 2004;171:752-756.²
A post hoc subgroup analysis of Van Kerrebroeck et al.
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*Source: IMS NPA, based on total US prescriptions of antimuscarinics for OAB from October 2001 to December 2005.

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