

Rapid test to screen for methicillin-resistant Staphylococcus aureus (MRSA)

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Editor's Note

Methicillin is no longer commercially available in the United States; however, providers and scientists still use the MRSA acronym to identify this type of bacteria.

In some British spellings, the antibiotic methicillin is meticillin.

Overview

Related Names

Proprietary Names: BACcelr8r; BacLite Rapid MRSA test; BBL Culture Swab; BD GeneOhm MRSA Assay; GeneXpert Dx; I-CORE thermocycler; IDI-MRSA; LightCycler; MagPhase; Mastalex-MRSA rapid slide latex kit; SmartCycler (16 I-CORE); StaphPlex panel; Xpert MRSA Generic Names: MRSA screening test; PCR; DNA hybridization

Technology Description

Rapid tests to screen for MRSA are molecular laboratory assays that can detect the bacteria's presence in a few hours. This form of testing minimizes or eliminates the need for time-consuming culturing, which takes 24 to 72 hours. Infection-control officers (i.e., hospital epidemiologists, infection disease specialists) use these tests to find individuals who could develop a life-threatening MRSA infection or transmit the bacterium to those at risk for serious MRSA infection. Hospitals determine screening criteria for MRSA by assessing infection risk and creating a screening policy. For screening, infection-control officers may target groups, including community members; people asymptomatic of MRSA; people who present to healthcare facilities; people exposed to patients with known MRSA-infection; and/or healthcare staff. Proponents believe rapid testing can detect MRSA carriers or body surfaces or cavities containing MRSA. Detecting MRSA allows for preventive steps that can decrease bacterial infection rates and lower overall costs to care for MRSA-infected patients.

Commercially available rapid test kits to screen for MRSA are composed of reagents, tubes with glass beads, and control DNA. This report focuses on the only two MRSA rapid assays currently available on the market in the United States—the BD GeneOhm MRSA Assay (BD Diagnostics-GeneOhm; San Diego, CA, USA; previously known as the IDI-MRSA Assay) and the Xpert MRSA Assay (Cepheid Inc., Sunnyvale, CA, USA). Both assays are laboratory tests indicated to detect MRSA directly from nasal specimens without requiring a culture. Test results are available in one to two hours.

To use the tests for screening, healthcare workers take nasal swab samples from each person to be tested. A laboratory technologist performs the assay using a real-time polymerase chain reaction (PCR) thermal cycling system (i.e., SmartCycler for BD GeneOhm MRSA Assay, GeneXpert Dx for Xpert MRSA).

The SmartCycler system is available in multiple combinations of 16-chamber test blocks that allow the testing of 16 to 96 specimens. The system includes a computer workstation with a flat panel monitor, software, tube racks, one heating-cooling block, and one mini centrifuge. The GeneXpert Dx system allows for concurrent testing of 16 specimens. The system includes a personal computer, software, and disposable fluidic cartridges. The system contains 2 to 4 randomly accessible modules that are capable of performing separate sample preparation and real-time PCR tests. Each module contains a syringe drive for dispensing fluids, an ultrasonic horn for lysing cells or spores, and an I-CORE thermocycler.

The time it takes to perform the assay and obtain results depends on the number of specimens processed in each batch. Batch testing in high-volume screening programs can increase resource efficiency.

Test results are reported as negative (no MRSA DNA detected), positive (MRSA DNA detected), unresolved (due to inhibitory specimen or reagent failure), or not determined (due to PCR module failure).

Care Setting

Ambulatory Surgery Center, Emergency Care, Inpatient, Outpatient, Public Access, Skilled Nursing Facility, Trauma Center

Disease/Condition

MRSA is a virulent multidrug-resistant strain of Staphylococcus aureus (SA), a bacterium commonly found in the nose and on the skin of healthy individuals. Providers and scientists still use the MRSA acronym for this strain, even though methicillin is no longer commercially available in the United States. MRSA is also resistant to common antibiotics such as oxacillin,



Quantity of Evidence Base

Seven clinical studies reporting on a total 4,104 samples taken from approximately 2,883 patients comprise the evidence base.



Quality of Evidence Base

Most of the clinical studies assessed only the test performance characteristics of the assay for detecting MRSA colonization, which has limited clinical applicability. Only one study assessed the clinical utility of using rapid testing for MRSA screening, and these data were not used to adjust infection control measures. Also, in four studies, use of multiple swabs concurrently taken from patients may have biased assay performance results.



Consistency of Evidence Base

Performance characteristics reported in six studies were fairly consistent: sensitivity of 81% to 100%, specificity of 90.2% to 98.6%, negative predictive value of 90% to 100%, and positive predictive value of 75% to 98%. Since only one study assessed the clinical utility of the test, consistency related to clinical utility could not be measured.

penicillin and amoxicillin. MRSA is easily transmissible through direct and indirect contact. MRSA can cause a wide range of infections including harmless pimples, pneumonia, surgical wound infections, and bloodstream infections. Since multiple manifestations of MRSA infections exist, no particular clinical signs or symptoms are determinant for diagnosis. Endogenous MRSA colonization can be asymptomatic; therefore, providers test samples from the usual site of MRSA colonization (i.e., nasal passages).

MRSA is classified into two subtypes according to the setting in which the bacteria are found: hospital-associated MRSA (HA-MRSA) and community-acquired MRSA (CA-MRSA). HA-MRSA infections are more common than CA-MRSA infections because open wounds, indwelling catheters, burns, and immune system deficiencies substantially increase the risk of symptomatic MRSA infection. However, preventing MRSA transmission is possible by several methods, including identifying MRSA carriers through active surveillance, practicing good handwashing techniques, and decontaminating surfaces using antibacterial disinfectants.

Topical antibiotics (e.g., mupirocin, retapamulin) are available to treat superficial MRSA infections and to decolonize asymptomatic carriers. Oral antibiotics (e.g., clindamycin, trimethoprim with sulfamethoxazole, tetracycline) are sometimes used to treat MRSA infections. If the infection persists, most MRSA infections are treatable with alternative antibiotics such as intravenous vancomycin and teicoplanin. More serious MRSA infections require treating the underlying condition (e.g., suppressed immunity, burns) in addition to using antibiotics.

Prevalence/Incidence Rate

The Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) conducted a national MRSA prevalence study in the United States in 2006. Data show that 46 out of every 1,000 patients included in the study were either infected or colonized with MRSA. This value is over 8 times higher than previous estimates. The APIC reports that MRSA accounts for 50% to 70% of the *Staphylococcus aureus* (SA) infections acquired in healthcare facilities.

An analysis of U.S. Centers for Disease Control and Prevention surveillance data (Klevens et al. 2007) reported that an estimated 94,360 cases of invasive MRSA occurred in 2005 in the United States, resulting in 18,650 deaths. The standardized incidence rate of invasive MRSA, 31.8 per 100,000 individuals, was much higher than case rates for other important invasive infections (i.e., *S pneumoniae*, *Haemophilus influenzae*).

The Healthcare Cost and Utilization Project (HCUP) reported about 368,600 cases of MRSA infection in U.S. hospitals in 2005. The highest rate of MRSA hospitalization was among the elderly, with 44% of all hospital inpatients with MRSA over the age of 65. Compared with patients without MRSA infections, a significantly larger proportion of patients in the hospital with MRSA infections tended to be 45 years of age and older.

Worldwide, MRSA is prevalent in many countries. Researchers in Sweden (Stenheim et al. 2006) reported an increased annual incidence rate of MRSA infections, from 3.7 to 6.1 per 100,000 people from 2000 to 2003. Researchers in the United Kingdom reported a 5% decrease in MRSA cases from between October 2005 to March 2006 and April 2006 to September 2006 (3,525 cases to 3,391 cases).

Manufacturers/Suppliers

The following rapid tests for MRSA are commercially available in the United States:

- BD Diagnostics, a division of Becton, Dickinson and Company (Franklin Lakes, NJ, USA), manufactures the BD GeneOhm MRSA Assay kit. The system is distributed in Canada, Europe, the Middle East, and the United States.
- Cepheid Inc. (Sunnyvale, CA, USA) manufactures the Xpert MRSA Assay kit, which runs on the GeneXpert Dx System. Cepheid also manufactures the SmartCycler (a real-time PCR thermal cycling system that is required to perform IDI-MRSA Assay kits) and the GeneXpert Dx (a real-time PCR system required to perform Xpert MRSA Assay kits).

The following rapid tests for MRSA are pending approval or are currently in development:

- 3M (St. Paul, MN, USA), in partnership with Gen-Probe Inc. (San Diego, CA, USA), manufactures the BacLite Rapid MRSA test, a culture-based system that detects bacteria by light output. The system was introduced in Europe in 2007, and will be introduced in the United States in 2008.
- Accelr8 Technology Corporation (Denver, CO, USA) is developing the BACcelr8r, a rapid clinical pathogen platform that can be used to identify MRSA.
- Blaze Venture Technologies (Hertfordshire, England) is developing a 10-minute test to screen patients for MRSA.
- Innovative Biosensors, Inc. (College Park, MD, USA) is using a light-based technology developed at Massachusetts Institute of Technology (Cambridge, MA, USA) to detect MRSA.
- Mast Group Ltd. (Merseyside, UK) manufactures the Mastalex-MRSA rapid slide latex kit for confirmation of MRSA.
- Roche Molecular Diagnostics (Indianapolis, IN, USA) has developed the LightCycler MRSA detection kit, which includes amplification and detection reagents for use on the LightCycler Instrument.
- Spinomix (Lausanne, Switzerland) has developed the MagPhase, a rapid diagnostic test platform to identify MRSA. The company is seeking partners to continue development.
- Quiagen (Valencia, CA, USA) manufactures the StaphPlex panel, a PCR-based assay that allows for MRSA identification for research application. The panel differentiates between community-associated MRSA and healthcare-associated MRSA.

In April 2007, BioMerieux SA (Marcy l'Etoile, France) initiated arbitration against GeneOhm Sciences Canada, a subsidiary of Becton Dickinson and Co. (San Diego, CA). BioMerieux is seeking to terminate a sublicense agreement where it granted certain patents to BD GeneOhm over a method of detecting MRSA. The arbitration proceeding was initiated through the International Chamber of Commerce.

Regulatory Status

Rapid testing to screen for MRSA in the United States is subject to regulation under the Clinical Laboratory Improvement Amendments (CLIA). Laboratories performing this testing must also comply with all federal, state, and local laboratory laws.

In March 2004, FDA provided GeneOhm Sciences with 510(k) marketing clearance for the IDI-MRSA Assay (now known as the BD GeneOhm MRSA Assay). In October 2004, FDA updated this clearance to include a 200-test format, modified reagents, modified PCR protocol, and upgraded software. The cleared indication is for in vitro use to detect MRSA colonies in nasal passages by means of swab specimens obtained from patients at risk of colonization. This test is categorized as a

high-complexity test. In 2003, Health Canada granted marketing approval for the IDI-MRSA Assay, and the assay received CE (Conformité Européene) mark approval, thus allowing commercial distribution of the testing kits in the European Union in 2004.

In April 2007, FDA provided Cepheid Inc. with 510(k) marketing clearance for the Xpert MRSA Assay. The cleared indication is for in vitro use to detect MRSA colonies in nasal passages by means of swab specimens obtained from patients at risk of colonization. This test is categorized as moderate complexity. The Xpert MRSA Assay received a CE mark in 2006, and Health Canada granted marketing approval for the assay in 2008.

Phase of Diffusion

Middle Diffusion

Phase of Diffusion Comment

The IDI-MRSA Assay (now known as the BD GeneOhm MRSA Assay) became commercially available in Canada, the European Union, and the United States in 2004. According to APIC, about 28% of hospitals are using active surveillance to identify patients carrying MRSA without active symptoms. Active surveillance involves testing most patients, including those who are not showing signs of infection. This requires collecting swabs, growing cultures, and testing them for resistance against key antibiotics.

The first U.S. hospital system to implement a universal MRSA screening program using a rapid test was Evanston Northwestern Healthcare (Evanston, IL, USA). This program began in August 2005, and the hospital is attempting to test every patient admitted. At the American Society for Microbiology's 46th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy in September 2006, investigators reported 1-year results of over 24,000 patients who had been tested at the Evanston site. A total of 5.4% of patients (1,309 patients) were found to carry MRSA, and infection rates were reduced by 60% within the first year.

In 2005, Veterans Affairs (VA) Pittsburgh Healthcare System (Pittsburgh, PA, USA) began using a rapid test for routine active surveillance of all entering patients. The prevalence of MRSA infections was reduced by 75% in 2006, and MRSA surgical-site infection rates fell by 50%. Since then, VA has begun phasing in MRSA testing at its 155 medical centers and plans to use rapid tests for all patients in 2008.

Because of state mandates for MRSA screening; expanding legislation that requires healthcare organizations to report healthcare-associated infection rates to the public; and CMS's decision to stop providing payment for hospital-acquired infections in late 2008, ECRI Institute expects widespread adoption of rapid testing to screen for MRSA.

Ongoing Clinical Trials

ECRI Institute searches did not identify any ongoing clinical studies in which scientists specified use of the BD GeneOhm MRSA Assay or the Xpert MRSA Assay in the available protocol summaries. However, we identified one ongoing study that used unidentified nasal swab and/or rapid tests to screen for MRSA. This interventional, nonrandomized study is evaluating the effectiveness of active surveillance (i.e., screening cultures) for MRSA colonization on nosocomial infections (NIs) and colonization rates. The study will compare NI and colonization rates in intensive care units (ICUs) between control and experimental groups and over time. This study began in April 2007 and is scheduled to end in September 2009.

Reported Patient Indications\Contraindications

Reported Patient Indications/Contraindications

Manufacturer Labeling

The BD GeneOhm MRSA Assay and the Xpert MRSA Assay are both indicated for in vitro use to detect MRSA colonies in nasal passages. Testing is intended to aid institutions in preventing and controlling MRSA infections in healthcare settings. The BD GeneOhm MRSA Assay is performed on the SmartCycler PCR instrument, and the Xpert MRSA Assay is performed on the GeneXpert Dx System.

Although the U.S. Food and Drug Administration (FDA) and other agencies refer to the assays as diagnostic for some purposes, the assay is intended neither to diagnose MRSA infections nor to guide or monitor their treatment. Parallel cultures (i.e., several cultures growing while rapid testing is done) are only necessary to recover organisms for subtyping or further susceptibility testing for epidemiology purposes.

Clinical Trial Participants

Clinical studies of the BD GeneOhm MRSA Assay that we assessed for this report incorporated one or more of the following inclusion criteria:

- hospital-admitted patients with prior MRSA infection or colonization;
- hospital-admitted patients with current hospital stay exceeding three days;
- hospital-admitted patients with known colonization or infection with any hospital-acquired pathogen;
- patients who were exposed to MRSA;
- patients > or = 18 years of age;
- patients who had transferred from another healthcare institution;
- patients with previous admission to any healthcare facility in the previous six months; and
- people living in areas of high risk for MRSA colonization.

These studies incorporated one or more of the following exclusion criteria:

- patients who had received treatment with intranasal mupirocin in the previous four days;
- patients who had received treatment with oral antimicrobials for the purpose of eradicating MRSA colonization within the past 14 days (including rifampin therapy); and
- patients who had received a MRSA-decolonization protocol.

Standards/Practice Guidelines

ECRI Institute searches identified the following three clinical guidelines and one position statement that include information on MRSA testing in general:

- U.S. Centers for Disease Control, Healthcare Infection Control Practices Advisory Committee: Management of multi-drug resistant organisms in healthcare settings. 2006. This guideline states, the impact of rapid testing for MRSA on the effectiveness of active surveillance as a prevention strategy has not been fully determined. In addition, this guideline provides recommendations for the implementation of MRSA surveillance in healthcare organizations and MRSA infection control.
- Joint Working Party of the British Society for Antimicrobial Chemotherapy, Hospital Infection Society and Infection Control Nurses Association: Guidelines for the laboratory diagnosis and susceptibility testing of MRSA. 2005. This guideline contains information on general SA tests and MRSA culture tests.
- Joint Working Party of the British Society of Antimicrobial Chemotherapy, Hospital Infection Society, Infection Control Nurses Association: Guidelines for the control and prevention of MRSA in healthcare facilities. 2006. This guideline includes information on conducting MRSA surveillance and screening; using antibiotics appropriately; intervening after positive screen test results; managing MRSA-infected patients; coordinating nursing staff; and understanding the financial impact.
- The Society for Healthcare Epidemiology of America (SHEA) and APIC: Legislative Mandates for Use of Active Surveillance Cultures to Screen for Methicillin-Resistant *Staphylococcus aureus* and Vancomycin-Resistant Enterococci: Position Statement from the Joint SHEA and APIC Task Force. 2007. According to this position statement, Although there is considerable evidence supporting the use of active surveillance cultures as a clinically effective and cost-effective method for combating the spread of antimicrobial resistant microorganisms in specific circumstances, to mandate this strategy as the single infection control intervention to be applied in all circumstances would preclude local risk assessment and the implementation of a broad range of interventions needed to control infections caused by antimicrobial-resistant and antimicrobial-susceptible pathogens.

ECRI Institute searches also identified the following three evidence reports related to this technology:

- U.K. National Horizon Scanning Centre; IDI-MRSA detection test for methicillin-resistant *Staphylococcus aureus* (MRSA) colonization - horizon scanning review. 2004. This report, which includes information on cost, patient groups, and test alternatives, found that the assay has 92.5% sensitivity and 96.4% specificity.
- A systematic review of the evidence for interventions for the prevention and control of methicillin-resistant *Staphylococcus aureus*: Report to the Joint MRSA Working Party (Subgroup A). 2006. This report found that insufficient, high-quality evidence exists for preventing and controlling MRSA infection. However, the report also found that evidence from clinically based, nonexperimental studies supports continued use of a combination of measures to prevent and control infection within acute hospitals and long-term care facilities.
- The National Health Service (NHS) Quality Improvement Scotland. The clinical and cost effectiveness of screening for MRSA. 2007. This report includes the following five recommendations:
 1. Conduct a primary study in acute patient care to assess whether screening all patients for MRSA is effective in preventing MRSA infection
 2. Research further the extent and implication of staff colonization
 3. Develop systems to collect patient-based data on the prevalence of MRSA colonization and infection
 4. Distribute high-quality patient information on MRSA to all patients and relatives upon admission to the hospital
 5. Assure that patients isolated due to MRSA colonization or infection not feel unnecessarily disadvantaged

Impact on Hospital Operations

Impact on Hospital Operations

Staffing

Laboratory technologists perform rapid testing. Infection-control officers typically administer a MRSA screening program and develop policies to minimize its transmission to patients and staff and to control infection outbreaks. In large institutions, these officers lead a team comprising infection control nurses who perform surveillance of hospital-acquired infections (NI). This team takes nasal swab samples from patients and investigates infection outbreaks. Institutions must ensure that the laboratory staff, infection control team, physicians, and other staff (e.g., nurses, environmental personnel) work in a coordinated manner to maintain and improve NI control.

Screening Policy

Before screening for MRSA, hospital infection-control officers must first assess the MRSA colonization risk of certain patient groups and the hospital in general. Historical information helpful to assess this risk includes hospital and local community MRSA colonization (i.e., prevalence) data, hospital MRSA infection rates, and a record of past screening and infection control measures. Based on a risk assessment and the goals and resources of the hospital, an infection control officer creates an institutional screening policy.

The breadth of MRSA screening policies varies. The most passive approach to MRSA control involves implementing contact isolation once MRSA has been identified, while a more aggressive approach includes active surveillance- screening all patients for MRSA on admission to a hospital. In the United States, some states (e.g., IL, NJ, PA) have legislation requiring hospitals to test for resistant bacteria in the highest-risk patients (e.g., those with a recent hospital stay, those admitted to ICUs) and those admitted from nursing homes. In some countries (e.g., the Netherlands, Scandinavian countries), institutions screen all patients and staff. In other countries, some institutions only screen high-risk patients, and some institutions do not screen patients at all.

Physical Setting Requirements

Rapid testing to screen for MRSA requires a clinical laboratory. Some laboratories use a separate room for PCR-related testing and require a tabletop centrifuge. The PCR testing room is ideally situated in close proximity to the clinical microbiology laboratory.

System Compatibility

Some clinical laboratories use specific results-reporting software. If laboratory directors want to import MRSA test result data into their general, clinical, periodic laboratory report, they must ensure software compatibility with the SmartCycler or

GeneXpert Dx system.

Quality Control Procedures

To ensure assay reliability, hospitals' clinical laboratories must perform periodic quality control testing (e.g., proficiency testing). CLIA, and some state governments, administer programs to assess interlaboratory reliability of clinical assays.

PCR-based laboratory assays involving amplified nucleic acids are prone to becoming contaminated, and thus may yield inaccurate results. Institutions must ensure that their infection control staff adheres to measures for preventing contaminated swab samples. They must also ensure that laboratory staff adhere to protocols for clean sample handling and use of assay reagents.

Test Throughput

Ongoing MRSA screening programs must determine in advance both the normal and maximum potential numbers of samples that will need processing each day. The number of rapid tests for MRSA that a laboratory may perform concurrently is limited to certain factors, including the capacity of the SmartCycler or GeneXpert Dx systems; the numbers of technicians trained on the procedure; and the laboratory workflow. A batch run can include a maximum of 96 individual samples. During infection outbreak investigations and/or high-risk screening, some institutions may restrict people with suspected MRSA exposure from patient areas until screening results are available. Therefore, complicated and/or large outbreaks may require the screening of substantially more samples than usual.

Reporting Regulations

Individual states may require clinical laboratories to report positive MRSA results even if they are obtained from a screening sample. At least twenty states (e.g., CA, CO, CT, DE, FL, IL, MD, MN, MO, NY, NJ, NH, OH, PA, RI, SC, TN, TX, VA, VE, WA) have enacted legislation that requires healthcare organizations to report healthcare-associated infection rates to the public. Several other states are considering this legislation, which may also include reporting of MRSA colonization rates.

Intervention Based on Test Results

NI control measures can vary substantially depending on many factors, including rapid test results, patient types, and hospital resources. Detailed descriptions of nosocomial MRSA infection-control programs that include screening are beyond the scope of this report. These risk-management programs can be complex and have substantial up-front costs. However, such programs may result in overall improved patient care and cost savings in the long-term.

Credentialing/Training

Infection Control Professionals

At least two U.S. professional societies provide education on hospital infection control:

- The Association for Professionals in Infection Control and Epidemiology (Washington, DC), and
- The Society for Healthcare Epidemiology of America (Alexandria, VA).

ECRI Institute searches identified one U.S. organization that certifies professionals in infection control and applied epidemiology. The Certification Board of Infection Control & Epidemiology, Inc. (CBIC) (Lenexa, KS) is a voluntary, autonomous, multidisciplinary board that provides direction for and administers the certification process. CBIC is independent from any other infection, control-related organization or association. To become certified, applicants must meet educational, practice, and examination requirements.

Laboratory and Institutional Accreditation

Apart from training and certifying professionals within institutions for infection control, the institutions and their laboratories are subject to accreditation by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). To become JCAHO-accredited, clinical laboratories must meet rigorous quality standards, including regularly self-assessing quality, passing an onsite survey, and meeting proficiency standards. The accreditation is intended to help a laboratory improve quality, reduce costs, and demonstrate accountability. For institutional-wide accreditation, JCAHO also has requirements governing infection control practices.

To receive Medicare or Medicaid payments, laboratories must have CLIA certification. To become certified, a laboratory must meet a number of CLIA regulations, including regular equipment calibration, personnel training, quality control, proficiency testing, record and specimen retention, and quality assessment.

Effect on Other Technologies

Complementary Technologies

Rapid tests to screen for MRSA complement measures intended to prevent transmission of infectious agents, such as the use of disinfectants, topical antibiotics, and isolation procedures. Continued use of these complementary measures is expected.

In some cases, rapid screening tests may complement diagnostic tests for MRSA infection. When a MRSA rapid test is positive, some providers order a standard MRSA diagnostic culture if a patient is showing symptoms of infection and/or if the patient has a certain, serious, underlying illness or condition (e.g., immune deficiency, cancer). In 2008, FDA approved an in vitro assay (BD GeneOhm StaphSR Assay; BD Diagnostics) that can detect SA and MRSA directly from a positive blood culture. Test results are available in one to two hours.

Competing Technologies

Rapid MRSA tests that do not require a culture step compete to some extent with rapid MRSA tests that require a culture step. For example, Acolyte Biomedica, Ltd. (Wiltshire, England) manufactures the BacLite flex assay that assesses samples from nasal swabs, but it requires a culture step and yields results in five to eight hours. Another rapid MRSA test, the MRSA-Screen latex (Denka Seiken, Ltd., Tokyo, Japan) yields a result in 15 minutes after an 18- to 24-hour culture step.

Although the rapid test kits that require a culture take longer to yield results, they cost less. In comparing rapid tests, institutions must weigh the cost differences and benefits of faster results (e.g., possible lower rates of transmission by reacting sooner to positive screen results). Results of cost-effectiveness modeling and/or clinical trials directly comparing

these technologies will drive decision making for infection-control programs.

Rapid tests to screen for MRSA may compete with or complement standard screening tests that require extended cultures. Some institutions use standard tests to confirm positive results from rapid tests. However, if ongoing studies demonstrate that rapid testing results in lower MRSA transmission rates, use of standard methods involving extended cultures will likely decline.

Cost and Reimbursement Issues

Device/Drug/Biotechnology/Service Costs

Assay Kits

BD GeneOhm MRSA Assay kits are available in two sizes: 48- and 200-test sizes. The list price for the BD GeneOhm MRSA Assay kit varies depending on the volume of patient samples. ECRI Institute could not identify specific list price or cost per result information for BD GeneOhm MRSA.

The Xpert MRSA assay kit, which includes 10 cartridges and the necessary reagents, costs \$274.00.

PCR Thermal Cycling System

The list prices of the SmartCycler system range from \$31,500 to \$63,000 depending on the instruments' concurrent test capability. These prices include a one-year service contract. An extended 2-year service contract costs about \$6,000.

ECRI Institute could not identify specific list price or cost per result information for the GeneXpert Dx system.

Additional Equipment

Laboratories require additional equipment to perform the BD GeneOhm MRSA or Xpert-MRSA Assays: a vortexer, heating and cooling blocks, and a high-speed centrifuge. This equipment is standard in most clinical laboratories. The list price for a vortexer ranges from \$500 to \$5,000, a cooling block is about \$350, a heating block is about \$500, and a high-speed centrifuge ranges from \$10,000 to \$30,000.

Disposable Supplies

The required, disposable supplies to perform this testing (i.e., gloves, gauze, sample transport medium) are typically available in any healthcare setting.

BD Diagnostics recommends BBL Culture Swabs with Liquid Stuart transport medium (Becton, Dickinson and Company), which cost about \$30 per lot of 250. Cepheid Inc. also recommends using their proprietary nasal swabs for which we were unable to find a specific cost.

Reimbursement

Coverage

In January 2007, The U.S. Centers for Medicare & Medicaid Services (CMS) issued a national coverage determination providing coverage for molecular MRSA tests for diagnostic testing. However, CMS reimbursement for MRSA screening tests is not well described.

ECRI Institute searches identified one private third-party payer that has a specific policy for the reimbursement of rapid tests for MRSA. Aetna considers PCR testing medically necessary to distinguish MRSA from nonresistant forms of SA.

Coding

The American Medical Association Current Procedural Terminology (CPT) Editorial Panel developed a 2007 CPT code for MRSA tests such as the IDI-MRSA Assay and the Xpert MRSA Assay. CPT codes facilitate, but do not guarantee, reimbursement.

Payment

According to the CMS clinical lab schedule for 2007, the national payment limit for infectious agent detection by nucleic acid (DNA or RNA) for MRSA using the amplified probe technique is \$49.00.

Cost Effectiveness & Considerations

Rapid-testing Surveillance

The total cost to conduct an ongoing MRSA rapid-test screening program varies depending on many factors, including screening policy and thoroughness of laboratory proficiency testing. An economic evaluation and modeling study (Ritchie et al. 2007) included in the NHS Quality Improvement Scotland evidence report assessed rapid testing for MRSA while assuming use of the BD GeneOhm MRSA Assay, equipment life of seven years, one swab sample taken per patient, and a setting in the United Kingdom. The study estimated a total testing cost-per-sample of 19.40 British pounds, which is approximately US\$40, and includes staffing, consumables, and overhead. The study also assessed cost-effectiveness of many other aspects of a MRSA control program, including screening via culture, contact precautions, and patient/staff decolonization.

MRSA Control Intervention

Control program measures beyond MRSA surveillance have many additional, possible costs, which include: administering nasal antibiotics; isolating patients; placing staff with positive screening results on leave; disinfecting patients and staff with special soaps; use of disposable blood pressure cuffs; and disinfecting rooms with surface cleaners.

Caring for MRSA-infected Patients

When creating a MRSA screening policy, institutions must also consider the costs related to caring for patients with MRSA infections. For example, one study (Shannon et al. 2006) reported a \$27,000 cost to care for a patient with a serious systemic MRSA infection. HCUP reported that average hospital stays for MRSA infections cost \$14,000, compared with \$7,600 for all other stays, and the length of hospitalization was more than double.

Evidence/Outcomes

Evidence Base

ECRI Institute performed a systematic search for published studies on rapid tests to screen for MRSA. To identify studies that would provide meaningful, interpretable data on relevant outcomes to assess the clinical utility of the technology, we included:

- studies that are either diagnostic cohort studies to evaluate the test's accuracy or controlled trials to evaluate the test's efficacy;
- studies that are published as a peer-reviewed full report. We excluded abstracts and meeting presentations, because they do not include complete results and sufficient detail about methodology to verify reported findings;
- studies that are published in English. Costs for translating foreign language articles into English are too high to be considered here;
- studies that specifically assessed rapid tests for screening MRSA that have received FDA clearance; and
- studies that assessed at least 100 individuals (patients, staff, and/or community members) in studies of test accuracy. Studies of test efficacy would need to enroll 1,000 or more patients per arm. Very small studies for detecting MRSA would likely be underpowered and thus unable to provide useful information on the accuracy or efficacy of the test.

ECRI Institute searches identified seven studies that met our inclusion criteria. Descriptions of these studies that assessed 4,104 samples in a total of 2,883 patients are below:

- Cunningham et al. (2007) performed an observational cohort study that assessed 1,305 patients in an adult critical care unit in the United Kingdom over a total of 11 months; 612 patients were screened using standard MRSA culture methods over a period of 5 months; and 693 patients were screened using the IDI-MRSA PCR test over 6 months. Outcomes of interest included carriage rate and MRSA transmission rates.
- de San et al. (2007) assessed 522 nasal specimens and 475 throat, perineum, and skin wound specimens from 466 patients admitted to a teaching hospital in Brussels. Investigators compared results of the MRSA rapid test to culture based, gold standard tests (i.e., enrichment broth).
- Oberdorfer et al. (2006) assessed nasal swabs of 320 ICU patients at a university hospital in Heidelberg, Germany. Investigators compared results of the MRSA rapid test to conventional culture of swabs from the nose, throat, and wounds.
- Desjardins et al. (2006) assessed 287 specimens from 150 patients at a hospital in Ottawa, Canada. Investigators evaluated the performance of the IDI-MRSA assay from pooled and unpooled specimens cultured in a selective broth. A total of 113 of the 287 specimens were either individual nasal swabs, rectal swabs, catheter-site wound swabs, or tracheal-site wound swabs. The other 174 specimens were analyzed as pooled nasal and rectal swabs.
- Bishop et al. (2006) assessed 576 swabs from 192 patients at a university teaching hospital in Melbourne, Australia. Investigators compared the relative sensitivities and specificities of the IDI-MRSA assay to detect MRSA colonization in nose and groin swabs when both specimens were processed separately and when both specimens were tested together. MRSA carriage rate was also reported.
- Huletsky et al. (2005) assessed 331 nasal specimens from 162 patients at high risk for MRSA colonization who were screened in a hospital MRSA surveillance program in Montreal, Canada. Investigators collected multiple specimens at weekly intervals from 66 of these patients. Data including antibiotic treatment received > or = 48 hours before MRSA screening (i.e., via nasal swab sampling) and MRSA risk-factor information were collected from all participating patients. Investigators compared MRSA rapid test results with a gold standard culture and testing protocol.
- Warren et al. (2004) assessed 288 patients at high risk for MRSA colonization admitted to a tertiary care hospital in St. Louis, MO. Investigators took nasal swab samples and compared results of the MRSA rapid test to two culture-based, gold-standard tests (i.e., direct plating, enrichment broth).

Limitations of this evidence base include the following:

- Clinical applicability: Most of the clinical studies assessed only the assay's test characteristics for detecting MRSA colonization. Only one study assessed the clinical utility of the MRSA rapid test. However, the use of data to adjust future infection control measures was not assessed.
- Sample independence: Analysis of data on a per-swab basis instead of on a per-patient basis when multiple swabs are taken from each patient may bias assay performance results. Four studies (Huletsky et al. 2005; Bishop et al. 2006; Desjardins et al. 2006; and de San et al. 2007) used this method.
- Potential investigator bias: Three studies received at least partial funding from the manufacturer of the IDI-MRSA Assay (Warren et al. 2004; Huletsky et al. 2005; and de San et al. 2007).

Reported Results/Outcomes

Diagnostic Performance Characteristics

The studies that assessed the diagnostic performance characteristics of rapid tests to screen for MRSA tested patient specimens using both a rapid test method and standard culture. Study investigators reported results for sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of each for diagnosing MRSA. Sensitivity is the percentage of true positives identified by a test. In these studies, sensitivity reflects the ability of rapid tests to correctly identify patients with MRSA. A diagnostic test with a high sensitivity is considered good, because it can identify most patients with a certain disease or condition. Specificity is the percentage of true negatives identified by a test and reflects the ability of rapid tests to correctly identify patients who do not have MRSA. The PPV of a test is the probability that a patient with a positive test actually has the condition, and the NPV is the probability that a patient with a negative test actually does not have the condition. High PPVs and NPVs for a test help to ensure that patients are given treatment when it is indicated and are spared unnecessary treatment.

The range of performance characteristics reported in the 6 studies were sensitivity of 81% to 100%, specificity of 90.2% to 98.6%, NPV of 90% to 100%, and PPV of 75% to 98% (Warren et al. 2004; and Huletsky et al. 2005; Bishop et al. 2006; Desjardins et al. 2006; Oberdorfer et al. 2006; and de San et al. 2007). Results from individual studies are listed below:

Sensitivity and Specificity: 91.7% and 93.5% (Warren et al. 2004); 100% and 98.4% (Huletsky et al. 2005); 83.3% to 90.0% (depending on the swab site), 91.7% (nose alone), 90.2% (groin alone), and 91.6% (nose and groin) (Bishop et al. 2006); 96% and 96% (Desjardins et al. 2006); 92.3% and 98.6% (Oberdorfer et al. 2006); and 81% and 97% (de San et

al. 2007).

NPV and PPV: 97.1% and 82.5% (Warren et al. 2004); 100% and 95.3% (Huletsky et al. 2005); 90% and 98% (Desjardins et al. 2006); 99.6% and 75% (Oberdorfer et al. 2006); and 97.9% and 75% (de San et al. 2007).

Clinical Utility

Cunningham et al. 2007 reported no significant difference in MRSA carriage rate between the rapid testing group and the culture group. The overall pre-admission carriage rate throughout the study was 7.0%. Monthly rates ranged from 3.6% to 10.8%, but specific numbers were not reported. The mean incidence of MRSA transmission was 4.90 per 1,000 patient days in the IDI-MRSA group and 13.89 per 1,000 patient days in the culture group (14 out of 693 patients versus 33 out of 612 patients respectively, p

Cautions and Complications

Rapid tests to screen for MRSA do not directly pose risks for patients. However, rare and minor risks associated with the nasal swabbing procedure (e.g., puncturing of the nasal mucosa, contaminating nasal passage from nonsterile swab) do exist.

Institutions must use rapid test results with caution in guiding decisions about infection-control measures for patients. This is important because rapid testing can sometimes produce false-negative or false-positive results. A false-negative result indicates no MRSA presence when it actually is present, and a false-positive result indicates MRSA presence when it actually is not present. False-negative or false-positive results can be caused by a test error such as a PCR cyclor malfunction. False results can also be caused by sampling errors such as incorrect nasal swabbing or cross-contaminated swabs. Using false-positive rapid test results to classify risk may lead to unnecessary patient isolation and other wasted resources. Using false-negative screening test results to classify patient risk levels can lead to increased transmission of MRSA infection to susceptible patients. Transmission can occur directly from infected patients or indirectly from staff. Some institutions isolate patients awaiting screening results.

Screening sampling methods are also important in interpreting test results. Using nasal swab samples may not reveal MRSA in a patient or healthcare worker who has MRSA colonies elsewhere in the body. In addition, a single screening test may not be representative of changing colonization.

ECRI Institute Conclusions

Rapid tests to screen for methicillin-resistant Staphylococcus aureus (MRSA) are intended to detect bacteria presence in the nasal passages of patients and healthcare staff. The two commercially available rapid tests in the United States (i.e., BD GeneOhm MRSA Assay, BD Diagnostics-GeneOhm, San Diego, CA, USA; and Xpert MRSA Assay, Cepheid Inc., Sunnyvale, CA, USA) do not require a culture and provide results within one to two hours. Results of rapid-screening MRSA tests may aid institutions in preventing and controlling MRSA infections.

Key clinical issues related to this technology's use are the test's ability to accurately detect nasal-colonized people and rule out those without colonization (i.e., sensitivity, specificity, negative predictive value [NPV], positive predictive value [PPV]) and the utility of the test results for hospital/healthcare facility infection control (reducing MRSA prevalence, infection, and mortality). The published evidence available to address some of these key issues consists of 7 clinical studies reporting on a total 4,104 samples taken from approximately 2,883 patients. Six of the clinical studies assessed only the diagnostic performance characteristics of rapid tests to screen for MRSA-tested patient specimens using both a rapid test method and standard culture. Study investigators reported results for sensitivity, specificity, PPV, and NPV of each for diagnosing MRSA. The results reported in these studies were sensitivities between 81% and 100%, specificities between 90.2% and 98.6%, NPVs between 90% and 100%, and PPVs between 75% and 98%. Only one study assessed the clinical utility of the MRSA rapid test. However, use of the data to adjust infection control measures was not assessed. Ongoing trials will likely provide useful information regarding the efficacy and cost-effectiveness of these tests to reduce MRSA infection rates, the clinical utility at the level of healthcare facilities, and specific departments such as the intensive care unit.

Key operational issues related to using this technology are test costs, laboratory equipment costs, and Clinical Laboratory Improvement Amendment (CLIA) requirements to perform high-complexity tests. The Xpert MRSA Assay kit costs \$274.00 for 10 cartridges and the necessary reagents. The polymerase chain reaction thermal cycling system required to perform the BD GeneOhm MRSA Assay ranges in price from \$31,500 to \$63,000 depending on the instrument's concurrent test capability. Laboratories performing this test must meet a number of CLIA regulations, including regular equipment calibration, personnel training, quality control, proficiency testing, record and specimen retention, and quality assessment.

The U.S. Centers for Medicare & Medicaid Services (CMS) issued a coverage decision on rapid tests to screen for MRSA. Screening falls under Medicare's statute on required benefits coverage (i.e., to provide benefits only for technologies that are medically necessary to diagnose or treat a disease or condition). Also, the American Medical Association has assigned a Current Procedural Terminology code for MRSA tests, such as the IDI-MRSA Assay and the Xpert MRSA Assay, which facilitates reimbursement for this screening test. According to the CMS clinical lab schedule for 2007, the national payment limit for this assay is \$49.00.

Rapid testing to screen for MRSA is just one aspect of a MRSA infection-control program. Hospital infection-control officers, laboratory technologists, physicians, and nursing staff must coordinate efforts to conduct a high-quality MRSA infection-control program. Preventing MRSA infections in hospitals can include conscientious hand-washing, isolating infected patients, and using disposable gowns and gloves in their rooms. Certification of infection-control officers and staff will probably improve the quality of MRSA infection control efforts. MRSA surveillance can be costly, but as part of a high-quality infection-control program, it may improve patient safety and care, and reduce overall costs related to treating MRSA infections. Because of state mandates for MRSA screening, legislation that requires healthcare organizations to report healthcare-associated infection rates to the public, and CMS's decision to stop providing payment for hospital acquire infections in late 2008, ECRI Institute expects widespread adoption of rapid testing to screen for MRSA.

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Classifications

Technology Class

Biotechnology

Clinical Category

Screening

Clinical Specialty

Clinical Laboratory, Dermatology, Diabetology, Healthcare Facility, Infectious Disease, Neonatal Intensive Care, Nursing Services, Senior Care/Geriatrics, Surgery, Trauma Unit/Services, Wound Care

UMDNS

Reagents, Molecular Assay, Infection, Bacteria, Staphylococcus aureus, Antimicrobial Resistant Strain, DNA [21-666]; Analyzers, Laboratory, Molecular Assay [20-668]

MeSH

Staphylococcus aureus; Methicillin Resistance; Staphylococcal Infections; Reagent Kits, Diagnostic; Polymerase Chain Reaction

ICD9

Infection with microorganisms resistant to penicillins [V09.0]; Staphylococcus aureus infection in conditions classified elsewhere and of unspecified site [041.11]

FDA SPN

SYSTEM, NUCLEIC ACID AMPLIFICATION TEST, DNA, METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS, DIRECT SPECIMEN [NQX]; KIT, SCREENING, STAPHYLOCOCCUS AUREUS [JWX]

SNOMED CT

Staphylococcus aureus [3092008]; Methicillin resistant Staphylococcus aureus [115329001]; Methicillin resistant staphylococcus aureus screening test [401289003]; Methicillin resistant Staphylococcus aureus infection [266096002]; Polymerase chain reaction [258066000]; Nucleic acid amplification [69363007]

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