

Contact: Barbara Kalavik
BD Public Relations
(201) 847-4209
Email: barbara_kalavik@bd.com

Key Research Papers Relevant to the BD GeneOhm™ MRSA Assay

Title & full summary

Arnold, M.S., Dempsey, J.M., Fishman, M., McAuley, P.J. Tibert, C., & Vallande, N.C. (2002). The best hospital practices for controlling methicillin-resistant *staphylococcus aureus*: On the cutting edge. *Infection Control and Hospital Epidemiology*, 23(2), 69-76.

<http://www.journals.uchicago.edu/ICHE/journal/issues/v23n2/4213/4213.web.pdf>

Short summary: Several Rhode Island hospitals saw a five-fold increase in MRSA incidence from 1995-2000. A performance improvement task force developed screening protocols, isolation techniques, methods of cohorting positive patients, and standardized surveillance methodologies. These were distributed to all Rhode Island hospitals in December 2001.

Details:

- From 1995-2000, several Rhode Island hospitals experienced a fivefold increase in nosocomial acquisition of MRSA.
- This study described efforts by a performance improvement task force of Rhode Island infection control professionals from five large acute care hospitals. This was set up to develop an epidemiologic model of consistent infection control practices to control MRSA.
- The model includes screening protocols, isolation techniques, methods of cohorting positive patients, decolonization issues, post-exposure follow-up, microbiology procedures, and standardized surveillance methodologies.
- The task force agreed that hospitals should standardize MRSA rates per 1,000 patient-days to track epidemiology; hospitals should monitor nosocomial MRSA rates and provide feedback to staff; intensive care units, residents of long-term-care facilities, and patients transferred between acute-care facilities are the greatest reservoirs for MRSA; hand hygiene practices must be used after caring for a patient who is MRSA positive; contact precautions are necessary to control spread of resistant organisms; an electronic “flagging” system should be in place to identify previously positive MRSA patients on readmission to a facility.
- The task force met with local infectious disease physicians and representatives from the Rhode Island Department of Health, the Hospital Association of Rhode Island, and Rhode Island Quality Improvement Partners.
- “Best practice guidelines” were finalized and distributed to all CEOs of Rhode Island hospitals by the Rhode Island Department of Health in December 2001, with the intent that hospitals will adopt them as best practices.

Key Research Papers

Clancy, M., Graepler, A., Wilson, M., Douglas, I., Johnson, J., & Price, C.S. (2006). Active screening in high-risk units is an effective and cost-avoidant method to reduce the rate of methicillin-resistant staphylococcus aureus infection in the hospital. *Infection Control and Hospital Epidemiology*, 27, 1009-1017.

http://www.journals.uchicago.edu/ucp/WebIntegrationServlet?call=ContentWeblet&url=http://www.journals.uchicago.edu/ICHE/journal/issues/v27n10/2005345/2005345.web.pdf?erFrom=1544024017535550393Guest¤t_page=content

Short summary: Active screening in high-risk units at University of Colorado Health Sciences Center found that 3.7% of ICU patients tested positive for MRSA. 91% of these patients would have been missed without active screening. The program saved some \$19,714/month in the ICUs, offering "an effective and cost-avoidant strategy for achieving a sustained decrease of MRSA infections."

Details:

- During a 15-month period, all patients admitted to University of Colorado Health Sciences Center adult medical and surgical ICUs were screened for MRSA nasal carriage on admission and then weekly.
 - The overall rate of MRSA infections for ICUs and general wards combined decreased from 6.1 infections per 1,000 census-days in the pre-intervention period to 4.1 infections per 1,000 census-days in the post-intervention period (P=.01).
 - A total of 3.7% of ICU patients were colonized or infected with MRSA on admission; 91% of these patients would have been missed without active screening.
 - At a cost of \$3,475/month for the program, the researchers averted an average of 2.5 MRSA infections/month for the ICUs combined, avoiding \$19,714/month in excess cost in the ICUs.
- Even in a setting of increasing community-associated MRSA, active MRSA screening as part of a multi-factorial intervention targeted to high-risk units may be an effective and cost-avoidant strategy for achieving a sustained decrease of MRSA infections throughout the hospital.

Key Research Papers

Cunningham, R., Jenks, P., Northwood, J., Wallis, M., Ferguson, S. & Hunt, S. (2006). Effect on mrsa transmission of rapid pcr testing of patients admitted to critical care. *Journal of Hospital Infection*, 65(1), 24-28.

http://www.sciencedirect.com/science?_ob=PublicationURL&_method=tag&_tockey=%23toc%236884%232006%23999359999.8998%23636647%23FLT%23&_auth=y&_version=1&refSource=toc&_pubType=J&_cdi=6884&view=f&count=361&subset=y&_subId=23639&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=0ed1249fb774b8ec9d0c4aef9dbc77d2

Short summary: This U.K. study of 1305 patients was performed in two separate phases and determined that use of the BD GeneOhm™ MRSA assay resulted in a faster time to detection with more rapid implementation of control measures thereby reducing the transmission of MRSA by 65% when compared with traditional, culture-based MRSA testing, (i.e., 13.9 transmissions/1000 patient days with culture detection vs. 4.9 transmissions/1000 patient days with BD GeneOhm™).

Details:

- The study shows the benefit of the BD GeneOhm™ MRSA assay compared with traditional culture-based methods in the critical care unit (CCU).
- The BD GeneOhm™ MRSA assay reduced the likelihood of transmission of MRSA by 65%, from an average of 13.9 transmissions per thousand patient days to 4.9 transmissions per thousand patient days.
- The study involved culture screening of 612 patients in April-August 2005, and PCR screening of 693 CCU patients between September 2005 and February 2006.
- The overall MRSA carriage rate was found to be 4.7% on admission; culture results were available in three working days, PCR results within one working day. Standard infection control precautions were used for patients who tested positive.
- "PCR screening for MRSA on admission to Critical Care Units is feasible in routine clinical practice, provides quicker results than culture based screening, and is associated with a significant reduction in subsequent MRSA transmission on the unit," Dr Cunningham and colleagues concluded.

Key Research Papers

Huang, S.S., Yokoe, D.S., Hinrichsen, V.L., Spurchise, L.S., Datta, R., Miroshnik, I. et al. (2006). Impact of routine intensive care unit surveillance cultures and resultant barrier precautions on hospital-wide methicillin-resistant staphylococcus aureus bacteremia. *Clinical Infectious Diseases*, 43, 971-978.

http://www.journals.uchicago.edu/ucp/WebIntegrationServlet?call=ContentWeblet&url=http://www.journals.uchicago.edu/CID/journal/issues/v43n8/39825/39825.html?erFrom=-5586624039424486967Guest¤t_page=content

Short summary: This U.S. study of an 800-bed facility over nine years showed that "MRSA screening allowed for early identification and isolation of MRSA carriers and decreased ICU-associated transmission by 47%."

Details:

- The study found that "routine MRSA surveillance, limited to ICUs at admission and on a weekly basis, resulted in marked ICU, non-ICU and hospital-wide reductions in MRSA bacteremia during prolonged observations in a non-outbreak setting."
- MRSA screening allowed for early identification and isolation of MRSA carriers and decreased ICU-associated transmission by 47%.
- "Routine screening for MRSA in ICUs, adopted after other recommended control measures were in place, prevented the majority of cases of MRSA bacteremia, both in ICUs and non-ICUs."
- For reducing MRSA bacteremia, "this intervention performed better than the introduction of alcohol hand rub as the primary means of hand disinfection and other nationally recommended infection control practices."
- In 16 months, the incidence density of MRSA bacteremia decreased by 75% in ICUs and by 40% in non-ICUs, leading to a 67% hospital-wide reduction in the incidence density of MRSA bacteremia.
- "Targeted surveillance for MRSA in high-risk units, combined with effective contact isolation procedures, may prevent large numbers of MRSA infection across an entire institution."

Key Research Papers

Shitrit, P., Gottesman, B.S., Katzir, M., Kilman, A., Ben-Nissan, Y., & Chowers, M. (2006). Active surveillance for methicillin-resistant *staphylococcus aureus* (mrsa) decreases the incidence of mrsa bacteremia. *Infection Control and Hospital Epidemiology*, 27, 1004–1008.
www.journals.uchicago.edu/ICHE/journal/issues/v27n10/2005369/brief/2005369.abstract.html

Short summary: Active surveillance culture is important for identifying hidden reservoirs of MRSA. A study at a 700-bed community hospital with endemic MRSA found incidence of MRSA bacteremia fell from 3.6 cases/month to 1.8 cases/month after the introducing active surveillance for all high-risk patients at admission.

Details:

- The study, by Pnina Shitrit *et al*, examined the impact of active surveillance culture for MRSA on incidence of nosocomial MRSA bacteremia in an endemic, 700-bed hospital.
- From July 2003 to October 2004, all high-risk patients were screened at admission; those who tested positive were placed in contact isolation and given one course of eradication treatment.
- The number of surveillance cultures performed increased from a mean of 272.57 cultures/month before the intervention to 865.83 cultures/month after the intervention.
- The percentage of surveillance cultures with positive results increased from 3.13% before to 5.22% after the intervention ($P < .001$).
- The mean number of MRSA bacteremia cases per month decreased from 3.6 cases before the intervention to 1.8 cases after the intervention ($P < 0.001$).
- Active surveillance culture is important for identifying hidden reservoirs of MRSA. Contact isolation can prevent new colonization and infection and lead to a significant reduction in morbidity and healthcare costs.

Key Research Papers

Vos, M.C., & Verbrugh, H.A. (2005). MRSA: We can overcome, but who will lead the battle? *Infection Control and Hospital Epidemiology*, 26(2), 117-120.
<http://www.journals.uchicago.edu/ICHE/journal/issues/v26n2/9876/9876.html>
<http://www.journals.uchicago.edu/ICHE/journal/issues/v26n2/9876/9876.web.pdf>

Short summary: This editorial – which was the lead article for the February 2005 issue of *ICHE* – asserts that, “Clearly, if we do battle, we will overcome even MRSA. Hospital epidemiologists and infection control professionals should be leading this battle, but in many places they ‘have not yet begun to fight.’”

Details:

- In the past two decades, MRSA has become “the most prevalent and important antimicrobial-resistant pathogen.”
- The authors note that “high rates of transmission are the consequence of patients’ increased susceptibility to acquisition combined with crowding and high rates of contact with healthcare workers.”
- The continuing spread of MRSA indicates that recommended preventive strategies have been either inadequate or improperly implemented.
- In regions where MRSA is highly endemic, it is difficult to determine exactly when and where transmission occurs. In contrast, in areas where prevalence of MRSA is low, it is possible to determine all people who have been in contact with an identified MRSA carrier and to test all contacts for MRSA.
- “This search for contacts together with isolation and treatment of carriers are cornerstones of the Dutch ‘search and destroy’ policy that has been so successful.” An important component of this approach is having a highly sensitive screen for detecting secondary carriers with a broad definition of what constitutes a contact.
- “Clearly, if we do battle, we will overcome even MRSA. Hospital epidemiologists and infection control professionals should be leading this battle, but in many places they ‘have not yet begun to fight.’ In such places, where MRSA infections have been allowed to spread out of control, hospital administrators or politicians may eventually begin to demand better control of this leading hospital pathogen.”

Key Research Papers

Warren, D.K., Liao, R.S., Merz, L.R., Eveland, M., & Dunne, W.M. (2004). Detection of methicillin-resistant *staphylococcus aureus* directly from nasal swab specimens by a real-time pcr assay. *Journal of Clinical Microbiology*, 42(12), 5578-5581.

<http://jcm.asm.org/cgi/content/full/42/12/5578?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=warren%2C+d&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>

Short summary:

This study – part of the FDA submission for the IDI-MRSA assay¹ – concludes that the test has a sensitivity of 91.7% and specificity of 93.5% compared to culture methods. The test “is sensitive and specific for the detection of MRSA directly from a swab specimen...and allows same day results, even with batching of specimens.”

Details:

- MRSA accounted for 57.1% of *Staphylococcus aureus* isolates from patients in 300 intensive care units (CDC National Nosocomial Infection Surveillance System).
- This study by David K. Warren of the Division of Infectious Diseases, Washington University School of Medicine (St. Louis, Missouri), and colleagues, evaluates the IDI-MRSA assay.
- “Rapid identification of MRSA colonization is critical to...infection control, with delays in detection resulting in either late institution of infection control measures and resultant occult transmission of MRSA between patients or unnecessary contact precautions being applied to high-risk patients, resulting in increased hospital cost.”
- Traditional methods for MRSA detection “require a culture step and the isolation of pure colonies that result in a minimum of 20 to 24 h until a result is known.”
- Samples from 288 patients were tested for MRSA using the IDI-MRSA assay, and with direct plating or enrichment broth selective culture methods. The IDI-MRSA assay showed 91.7% sensitivity, 93.5% specificity, 82.5% positive predictive value and 97.1% negative predictive value, compared with culture-based methods.
- The time from the start of processing of specimen to result was around 1.5 hours.
- “The IDI-MRSA assay demonstrated a sensitivity and specificity above 90% for the detection of MRSA nasal colonization compared to two selective culturing methods. The assay can be performed by a single technologist, after receiving appropriate training, and allows same-day results with batching of specimens.”
- The assay “is a sensitive and specific test for detection of nasal colonization with MRSA and providing for same-day results, allowing more efficient and effective use of infection control resources to control MRSA in health care facilities.”
- This study was part of the FDA submission for the IDI-MRSA assay.

¹ Now known as the BD GeneOhm™ MRSA Assay

Key Research Papers

West, T.E., Guerry, C., Hiott, M., Morrow, N., Ward, K. & Salgado, C.D. (2006). Effect of targeted surveillance for control of methicillin-resistant *staphylococcus aureus* in a community hospital system. *Infection Control and Hospital Epidemiology*, 27(3), 233–238.

<http://www.journals.uchicago.edu/ICHE/journal/issues/v27n3/2004316/2004316.html>

Short summary: This study showed that MRSA screening in two hospitals prevented an estimated 13 MRSA bacteremias and nine surgical site infections, which would have cost the system \$1.5 million.

Details:

- This paper concluded that “targeted surveillance for MRSA colonization was cost-effective and provided substantial benefits by reducing the rate of nosocomial MRSA infections in a community hospital system.”
- “Surveillance was cost-effective, preventing 13 nosocomial MRSA bacteremias and 9 surgical site infections, for a savings of \$1,545,762.”
- The study covered patients in a 400-bed tertiary-care facility (Roper Hospital) and a 180-bed suburban hospital (St. Francis Hospital), both in Charleston, South Carolina.
- The mean rate of nosocomial MRSA infection decreased at Roper (0.76 cases per 1,000 patient-days before and 0.45 per 1000 patient-days after initiation of expanded surveillance) and at St. Francis (0.73 cases per 1,000 patient-days before and 0.57 cases per 1000 patient-days after).
- Surveillance was cost-effective, preventing 13 nosocomial MRSA bacteremias and 9 surgical site infections, for a savings of \$1,545,762.
- Used swab samples from the anterior nares of patients in ICUs for MRSA surveillance cultures. When no change in infection rates was seen, both hospitals began targeted MRSA surveillance of all at-risk patients throughout the hospital.
- Patients found to be colonized or infected with MRSA were placed in contact isolation.
- Costs of surveillance were estimated at \$6.83 for a culture with negative results and \$10.36 for a culture with positive results. “Our clinical microbiology laboratory used oxacillin salt agar plates to screen for MRSA.”