FROM THE CENTERS FOR DISEASE CONTROL AND PREVENTION

MMWR
Morbidity and Mortality Weekly Report

# *Pseudomonas aeruginosa* Respiratory Tract Infections Associated With Contaminated Ultrasound Gel Used for Transesophageal Echocardiography—Michigan, December 2011–January 2012

*MMWR. 2012;61:262-264*

*1 table omitted*

IN LATE DECEMBER 2011, THE DEPARTMENT of Epidemiology at Beaumont Health System (BHS) in Royal Oak, Michigan, noted an increase in the number of positive respiratory cultures in one surgical intensive-care unit (ICU), prompting further investigation. The increase in positive cultures was attributed entirely to *Pseudomonas aeruginosa*. Investigation by BHS staff members found that all of these positive cultures were related to use of ultrasound transmission gel from a single manufacturer during transesophageal echocardiography. Seven patients were infected with *P. aeruginosa* based on National Healthcare Safety Network (NHSN) criteria,[1] and nine were colonized. Cultures from one open and one unopened bottle of the gel grew *P. aeruginosa* closely related to the outbreak strain based on molecular typing via repetitive extragenic palindromic polymerase chain reaction (rep-PCR). The Oakland County Health Department, the Michigan Department of Community Health, and the Food and Drug Administration (FDA) were notified of the findings. On January 23, all implicated ultrasound gel in multiuse bottles was removed from BHS facilities and replaced with a single-use, sterile ultrasound gel for all potentially invasive procedures. On April 18, FDA issued a Safety Communication* advising health-care professionals and facilities not to use certain lot numbers of the ultrasound transmission gel and further advising that the only ultrasound gel that is sterile is unopened gel in containers labeled as sterile. To date, no further respiratory cultures have been positive for *P. aeruginosa*.

Surveillance for nosocomial infection at BHS is driven by results of clinical microbiology cultures. Positive cultures are reviewed using a combination of microbiology reports and paper or electronic medical records to determine infections and colonizations. Initial review found *P. aeruginosa* in respiratory specimens taken from endotracheal tubes in 10 patients in a single surgical ICU in December. No cultures of these patients' surgical sites or blood grew *P. aeruginosa*. The same unit had averaged less than three respiratory tract cultures positive for *P. aeruginosa* monthly during the preceding 11 months and had only one infection by NHSN criteria during that period.

Review of the 10 *P. aeruginosa* cultures revealed that all patients had undergone cardiovascular surgery. No clustering by operating room, surgeon, operating room staff member, ICU room number, or nursing staff was observed. Because all isolates were from the respiratory tract, the initial focus included a review of postoperative nursing and respiratory-care practices, respiratory therapy equipment management, and anesthesia practice and equipment management. No clustering by respiratory medications administered was observed. Discussion with operating room staff members revealed that a unique aspect of these patients' surgeries included the use of an intraoperative transesophageal echocardiogram (TEE). TEEs involve the insertion of a probe with an ultrasound conducting tip into a patient's esophagus and are used during cardiovascular surgery to aid in visualization of the posterior of the heart. The TEE probe is coated with a coupling gel and then inserted by an anesthesiologist before surgical incision. Their duration of placement depends on the specific procedure being performed. Environmental cultures of TEE probes, storage tubes, and work surfaces were performed, and all TEE probes were inspected. All cultures were negative, and only one probe had a mechanical defect; this probe was removed from use.

Intensified surveillance (performing respiratory tract cultures on all mechanically ventilated patients in this surgical ICU) during January 6-20 identified six additional patients colonized with *P. aeruginosa* (of the 20 patients tested). All

### What is already known on this topic?

Medical gels have been linked to outbreaks of infection in several reports, including reports of gels contaminated at the site of packaging. As a result, Health Canada in 2004 issued recommendations for minimizing the risk for infection from medical gels. No such guidelines exist in the United States.

### What is added by this report?

An outbreak of seven cases of *Pseudomonas aeruginosa* respiratory tract infection and nine instances of respiratory tract colonization was linked to contaminated ultrasound gel. *P. aeruginosa* isolates found in 10 patients, one of four opened gel bottles in use in the operating room, and one of two unopened, sealed gel bottles were found to be more than 99% similar by molecular typing.

### What are the implications for public health practice?

Because of the risk that an ultrasound gel might be contaminated with *P. aeruginosa* or other bacteria, single-use, sterile products should be used for invasive procedures and procedures involving contact with nonintact skin or mucous membranes.

six of these patients also had undergone cardiovascular surgery. Surveillance respiratory cultures from another surgical ICU identified only one patient colonized (of the 11 patients tested) with *P. aeruginosa*; this isolate had a different antibiotic susceptibility pattern from those of the 16 isolates found earlier. Of the 16 patients identified during the outbreak, two had pneumonia, five had tracheobronchitis, and nine had respiratory tract colonization only. Time from surgery to identification of a positive culture from a respiratory tract specimen ranged from 2 to 14 days (median: 5 days). The patients had undergone various surgical procedures. Those who had undergone valvular surgery alone (n=13) were at significantly higher risk (relative risk=5.7, 95% confidence interval=1.75-18.86) for *Pseudomonas* infection or colonization than those who had undergone coronary artery bypass grafting alone (n=32). The investigation noted that patients undergoing valvular surgery have TEE probes in place during nearly the entire procedure, whereas those undergoing coronary artery bypass grafting had shorter durations of TEE use. A review of operative times found that procedures lasting ≥5 hours (n=70) were more frequently associated with *P. aeruginosa* infection or colonization (relative risk=6.4, 95% confidence interval=0.89-46.45) than procedures lasting <5 hours (n=30).

The investigation focused further on manipulations of the respiratory and gastrointestinal tract. An ultrasound transmission gel, Other-Sonic (Pharmaceutical Innovations, Inc., Newark, New Jersey), which was not labeled or sold as a sterile product, was used with TEE probes. The multidose containers of gel were collected and replaced with a single-use, sterile product on January 23. After this change, no additional respiratory cultures with *P. aeruginosa* were observed.

Molecular typing was performed on the 10 isolates on January 26, and all were determined to be >99% similar by rep-PCR. Cultures of the four previously opened Other-Sonic ultrasound transmission gel bottles removed from the operating room were performed; one of four samples grew *P. aeruginosa*, and molecular typing revealed it to be highly related (>99%) to the outbreak strain. Five other strains of *P. aeruginosa* isolated throughout the hospital during the outbreak period also were analyzed and determined to be unrelated to each other or the outbreak strain. Two bottles of sealed, unopened Other-Sonic ultrasound transmission gel subsequently were cultured, one of which grew *P. aeruginosa*. At this point a health-care system—wide recall of all bottles of Other-Sonic ultrasound transmission gel was initiated, local and state health departments were contacted, and FDA was notified. Additional molecular typing studies (using rep-PCR) showed that the *Pseudomonas* isolate from the sealed bottle also was >99% similar to the outbreak strain, strongly suggesting contamination of the product during manufacturing, packaging, storage, or shipping.

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**Editorial Note:** This report describes an outbreak of *Pseudomonas aeruginosa* respiratory tract colonization and infection related to the use of contaminated ultrasound transmission gel. Sixteen cardiovascular surgery patients were affected during the outbreak, seven with infection per NHSN criteria, and nine with colonization. Initial investigation suggested the possibility that the TEE probes were the source of the outbreak, given that contaminated TEE probes have been linked to pulmonary infection outbreaks of Legionella previously.[2] However, surveillance cultures of the probes were negative, and there was no evidence that all case patients were linked to the use of a particular probe. The ultrasound transmission gel, however, was contaminated with *P. aeruginosa*. Although contamination during use was initially suspected, the fact that one of two tested bottles of sealed, unopened product was contaminated with *P. aeruginosa* suggests that the contamination might have occurred before the product reached BHS.

Contaminated ultrasound gels have been associated with outbreaks of infection in various settings and with various organisms, including *Klebsiella*,[3] *Burkholderia*,[4,5] *Achromobacter*,[6] and *Staphylococcus aureus*.[7] Although most of these outbreaks were believed to have occurred from inappropriate use of products, in one circumstance it was determined that the gel had been contaminated at the site of production.[4] Although these gels contain parabens or methyl benzoate, which are thought to render them bacteriostatic, some Gram-negative bacteria can degrade these components,[4] and investigations of several reported outbreaks suggest extrinsic contamination of gels might easily occur.[3,5-7] One study demonstrated that an ultrasound gel had no intrinsic antimicrobial properties,[8] and interestingly, results of another in vitro study suggested *Pseudomonas* spp. might actually survive for shorter periods in ultrasound gel compared with *S. aureus* or *Escherichia coli*.[9] No ingredient information is available publicly for Other-Sonic ultrasound gel.

Numerous products are available to be used as ultrasound transmission gels. No national guidelines exist in the United States recommending specific types of gel for specific procedures. However, in 2004, Health Canada issued recommendations for minimizing the health risks of using gels.[10] These recommendations suggested use of single-use, sterile gels for invasive procedures that pass through a tissue, for all studies involving neonates, for all procedures involving sterile equipment or non-intact skin, and for procedures on intact mucous membranes. The results of this report further support a recommendation for the use of only sterile gels for invasive procedures and procedures involving contact with nonintact skin or mucous membranes. Moreover, because only unopened ultrasound gel containers labeled as sterile should be considered sterile and extrinsic contamination might easily occur,

only single-use sterile products should be used for such purposes.

**Acknowledgments**

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**REFERENCES**

10 Available.

*Available at http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm299409.htm.

# Reducing Bloodstream Infections in an Outpatient Hemodialysis Center—New Jersey, 2008-2011

*MMWR. 2012;61:169-173*

*2 tables omitted*

PATIENTS UNDERGOING HEMODIALYSIS ARE at risk for bloodstream infections (BSIs), and preventing these infections in this high-risk population is a national priority.[1] During 2008, an estimated 37,000 BSIs related to central lines occurred among hemodialysis patients in the United States. This is almost as many as the estimated 41,000 central line—associated BSIs that occurred during 2009 among patients in critical-care units and wards of acute-care hospitals. In 2009, to decrease BSI incidence in a New Jersey outpatient hemodialysis center, a package of interventions was instituted, beginning with participation in a national collaborative BSI prevention program and augmented by a social and behavioral change process to enlist staff members in infection prevention. Rates of BSIs related to the patient's vascular access (i.e., access-related BSIs [ARBs]) were evaluated in the preintervention and postintervention periods. The incidence of all ARBs decreased from 2.04 per 100 patient-months preintervention to 0.75 ($p=0.03$) after initiating program interventions and to 0.24 ($p<0.01$) after adding a behavioral change intervention. Only one ARB occurred during the last 12 postintervention months. At this hemodialysis facility, participating in a collaborative prevention program along with implementation of a behavioral change strategy was associated with a large decrease in ARBs. Other outpatient hemodialysis facilities also might reduce ARBs by adopting similar approaches to prevention.

To address BSI prevention in outpatient hemodialysis centers, CDC established the CDC Hemodialysis BSI Prevention Collaborative in mid-2009. As part of this effort, member hemodialysis centers report BSIs to the National Healthcare Safety Network and adopt a uniform package of BSI prevention interventions.* Participating facilities also can implement a "positive deviance" approach to social and behavioral change† to engage staff members in these efforts and thereby improve adherence to recommended interventions. A premise of positive deviance is that in most communities or organizations, uncommon (deviant) practices of persons or groups within the organization can yield better (positive) results (e.g., better adherence to recommended practices) than traditional practices of their peers who have access to the same resources.[2] The process helps members of an organization identify, generate, and diffuse positive deviant practices.

The dialysis unit at AtlantiCare Regional Medical Center is a 12-station, hospital-based outpatient hemodialysis center serving patients in Atlantic City, New Jersey, and the surrounding region. Several interventions already were in place to reduce BSIs before introduction of the prevention program and positive deviance; despite this, BSI incidence remained above facility goals. The facility joined the collaborative in September 2009 and during the next 3 months worked to implement the collaborative's prevention program interventions, which included, in addition to dialysis event surveillance, (1) observation of catheter care and vascular access care, (2) use of chlorhexidine for skin antisepsis, (3) auditing of hand hygiene adherence, (4) patient education and engagement, (5) catheter use reduction programs, and (6) staff member education and competency testing. Program members also participated in monthly telephone conferences and yearly face-to-face meetings that served as a forum for presenting infection prevention topics, sharing best practices, and problem solving.

The positive deviance process was introduced to leaders from the medical center and dialysis center in early 2010. Two identical kick-off sessions were held in August 2010 to orient dialysis staff members and support personnel to positive deviance. After the kick-off sessions, discovery and action dialogue sessions were held.[3] These sessions were designed to tap the expertise of front-line staff members, identify positive deviant practices and their potential use, and encourage staff members to take personal responsibility for BSI prevention. For example, one nurse used a mnemonic device to achieve near-perfect hand hygiene compliance, which she taught to the other nurses. To assess and

**What is known on this topic?**

In 2008, an estimated 37,000 bloodstream infections (BSIs) related to central lines occurred among hemodialysis patients in the United States. Despite national decreases in BSIs in other health-care settings, the incidence of these infections in dialysis settings does not appear to be decreasing.

**What is added by this report?**

At one dialysis center, participation in the CDC Hemodialysis BSI Prevention Collaborative, use of collaborative interventions, and introduction of a social and behavioral change process (positive deviance) were associated with significant reductions in BSIs that were related to the patient's vascular access.

**What are the implications for public health practice?**

Health-care—associated infections, including BSIs, are an ongoing hazard for patients who receive their care primarily as outpatients. Based on the success at this facility and the success of similar programs in other health-care settings, the approach described in this report might be effective in other outpatient dialysis facilities to prevent BSIs.