

Contaminated Ultrasound Gel Tied to Outbreak of Healthcare-Associated Infections

Society for Healthcare Epidemiology of America

After a 2011 outbreak of *P. aeruginosa*, investigators at Beaumont Health System near Detroit, Michigan determined contaminated ultrasound gel was the source of bacteria causing the healthcare-associated infection. The findings emphasize the need for increased scrutiny of contaminated medical products. This study is published in the August issue of *Infection Control and Hospital Epidemiology*, the journal of the Society for Healthcare Epidemiology of America.

"Ultrasound is a critical healthcare tool used every day in both diagnostic and interventional procedures," said Paul Chittick, MD, lead author of the study. "Although contaminated gel has been the cause of several documented outbreaks of infection, its potential role as a vehicle for spreading infections to patients is frequently overlooked."

In December 2011, researchers uncovered an unusual cluster of *P. aeruginosa* in the cardiovascular surgery intensive care unit during routine infection control surveillance. The bug is known to increase the risk of bloodstream and respiratory infections in immune-compromised individuals. Sixteen patients became colonized or infected with the bacteria, with all cases occurring in the respiratory tract. The outbreak was found to have stemmed from bottles of ultrasound transmission gel used during cardiovascular surgery. Following replacement of this gel with a sterile product, no further cases occurred.

Cultures of gel from a bottle in use in the operating room grew *P. aeruginosa* that was identical to the outbreak strain. It was originally thought that the gel had likely become contaminated during use. However, sealed bottles of gel grew the same *P. aeruginosa* strain, proving that the product was contaminated during the manufacturing process at the plant of Pharmaceutical Innovations.

As a result of this investigation, the FDA issued a warning about the gel, alerting the risk of infection posed by the product and instructing healthcare providers and systems not to use the infected products.

The Beaumont Health System investigators also recently published proposed guidelines in *Infection Control and Hospital Epidemiology* for the use of sterile versus nonsterile ultrasound gel. These guidelines include the need for sterile, single-dose ultrasound gel to be used for all invasive procedures and give appropriate storage and warming methods for the gel. Prior to this, no such guidelines existed in the United States.

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