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Notes from the Field: *Mycobacterium chimaera* Contamination of Heater-Cooler Devices Used in Cardiac Surgery — United States

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In the spring of 2015, investigators in Switzerland reported a cluster of six patients with invasive infection with *Mycobacterium chimaera*, a species of nontuberculous mycobacterium ubiquitous in soil and water. The infected patients had undergone open-heart surgery that used contaminated heater-cooler devices during extracorporeal circulation (1). In July 2015, a Pennsylvania hospital also identified a cluster of invasive nontuberculous mycobacterial infections among open-heart surgery patients. Similar to the Swiss report, a field investigation by the Pennsylvania Department of Health, with assistance from CDC, used both epidemiologic and laboratory evidence to identify an association between invasive *Mycobacterium avium* complex, including *M. chimaera*, infections and exposure to contaminated Stöckert 3T heater-cooler devices, all manufactured by LivaNova PLC (formerly Sorin Group Deutschland GmbH) (2). *M. chimaera* was described as a distinct species of *M. avium* complex in 2004 (3). The results of the field investigation prompted notification of approximately 1,300 potentially exposed patients.* Although heater-cooler devices are used to regulate patients' blood temperature during cardiopulmonary bypass through water circuits that are closed, these reports suggest that aerosolized *M. chimaera* from the devices resulted in the invasive infections (1,2). The Food and Drug Administration (FDA) and CDC have issued alerts regarding the need to follow updated manufacturer's instructions for use of the devices, evaluate the devices for contamination, remain vigilant for new infections, and continue to monitor reports from the United States and overseas (2).

Whole genome sequencing was completed on isolates from 11 patients and from five Stöckert 3T heater-cooler devices from hospitals in Pennsylvania and Iowa, two of the states where clusters of infections were identified (2). Samples from heater-cooler devices included swabs from the interior of the device, water drained from the devices, and air samples collected while a device was operating. Single nucleotide polymorphisms (SNPs) were identified after comparing patient and device samples against sequence data from an *M. chimaera* reference isolate. Results from pairwise comparisons among all sequences across a core genome of approximately 5 million base pairs revealed a maximum of 38 SNPs between any two isolates related to the outbreak investigation, versus a minimum of 2,900 SNPs between any single outbreak isolate and the epidemiologically unlinked isolate (sequence files available from the National Center for Biotechnology Information: Pennsylvania isolates Bioproject PRJNA344472; Iowa isolates Bioproject PRJNA345021; epidemiologically unlinked isolate RefSeq Assembly Accession GCF_001307335.1).

These results strongly suggest a point-source contamination of Stöckert 3T heater-cooler devices with *M. chimaera*. A recent report from Germany noted that preliminary typing results of *M. chimaera* from heater-cooler devices from three different European countries were almost identical to samples obtained from the manufacturing site, further supporting the likelihood of point-source contamination (4). Additional sequence comparisons between patient specimens and device samples obtained from facilities from various regions in the United States are ongoing. Sequence comparisons between U.S. and European samples, as well as samples from the manufacturing site, could provide additional information for evaluating the possibility of point-source contamination at the heater-cooler manufacturing site. Efforts are currently ongoing to obtain and compare European sequencing results.

Although thousands of patients in the United States have been notified regarding potential exposure to contaminated heater-cooler devices, the number who were exposed might be much larger. Over 250,000 procedures using cardiopulmonary bypass are performed in the United States each year (5). Stöckert 3T heater-cooler devices represent approximately 60% of the U.S. market (2). CDC and FDA are continuing their efforts to increase provider and patient awareness of the risk. CDC has issued guidance on identifying patients at risk to ensure timely diagnosis and treatment of these indolent and often unrecognized infections (2). FDA is continuing to gather information, issue communications, and assess the situation from both public health and regulatory perspectives (6).[†]

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* <https://www.wellspan.org/news/story/15810> ↗.

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[†] <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/UCM520191.htm> ↗.

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