

More than a third of heater-cooler devices used in open heart surgery may be contaminated with deadly bacteria

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Thirty-three of 89 (37 percent) heater-cooler units assessed between July 2015 and December 2016 tested positive for *Mycobacterium chimaera* (*M. chimaera*), a bacterium associated with fatal infections in open-heart surgery patients, according to new research presented at the 44th Annual Conference of the Association for Professionals in Infection Control and Epidemiology (APIC).

Heater-cooler units (HCUs) control the temperature of a patient's blood and organs during [heart bypass surgery](#). The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) previously have issued safety warnings that a widely used brand of HCUs might be contaminated during manufacturing, putting patients at risk for life-threatening infections. Approximately 60 percent of [heart bypass](#) procedures performed in the U.S. use the brand of device associated with these infections.

The research, presented by John Rihs, VP of Laboratory Services at Special Pathogens Laboratory, advanced knowledge about the extent of colonization of *M. chimaera* that might be present in these units. Rihs and colleagues assessed devices already in use for the presence of non-tuberculous mycobacteria (NTM) colonization (primarily *M. chimaera*) in HCUs before and after decontamination. A total of 653 water samples from 89 units were tested. Samples were received from 23 hospitals in 14 states, the District of Columbia, and Canada. Thirty-three of the units

(37 percent) tested positive for *M. chimaera*, while four units were colonized with *Legionella*. Researchers were surprised at how contaminated the units were, with 97 cultures deemed uninterpretable due to high levels of bacterial and fungal contamination. Multiple other strains of mycobacteria were also detected in many of the units.

"Our results showed *M. chimera* in 37 percent of units tested and is consistent with previous findings. The extent of contamination from such a rare organism in multiple units from all over the country was surprising," said Rihs. "Some devices remained positive for *M. chimera* for months, indicating that disinfection can be difficult and routine testing is advisable. Beyond *M. chimera*, we found other NTM species, *Legionella*, and fungi, indicating these units are capable of supporting a diverse microbial population."

HCU's have water tanks that provide temperature-controlled water during surgery through closed circuits. The water in the instrument does not come into direct contact with the patient. However, the water can aerosolize, and if contaminated, transmit bacteria through the air into the environment, and to the patient.

"These results highlight the importance of monitoring the decontamination and maintenance schedules of these devices to minimize the risk of patient harm," said Linda Greene, RN, MPS, CIC, FAPIC, 2017 APIC president. "Hospitals must follow the cleaning and disinfection instructions provided in the manufacturer's device labeling, as well as updated communications from the FDA and CDC."

M. chimaera is often found in soil and water but is rarely associated with infections. However, patients exposed to the bacteria through [open-heart surgery](#) can develop general and nonspecific symptoms that can often take months to emerge. As a result, diagnosis of these infections can be missed or delayed, sometimes for years, making these infections more

difficult to treat.

Hospitals were instructed by the CDC and FDA to notify patients who have had open-heart surgery within the last five years that they were potentially at risk for [infection](#). Patients were notified to seek medical advice if they were showing any symptoms or signs of infection, which can be vague or inconspicuous.

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