

Going the extra mile



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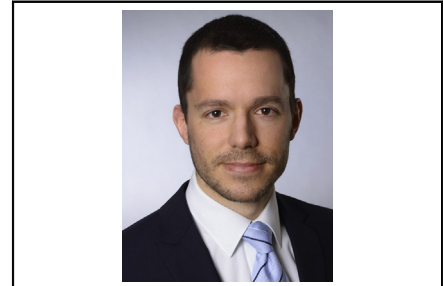
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Central Message

Heater-cooler devices are associated with mycobacterial infections, but these are difficult to track. Rigorous clinical protocols, epidemiologic investigations, and device improvements are necessary.

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In 2014, researchers at the Mayo Clinic reported an unusual occurrence of surgical site infections caused by *Mycobacterium wolinskyi* and suggested that heater-cooler units used in cardiothoracic procedures were the potential source.¹ Although others previously identified nontuberculous mycobacterial (NTM) infections after cardiac surgery as well, Sax and colleagues² were finally able to provide evidence supporting the association of *Mycobacterium chimaera* colonization of heater-cooler units and infections after cardiothoracic procedures by strain typing. As a consequence, the Food and Drug Administration issued a safety communication and recommendations for the prevention of NTM infections.^{3,4} More than 100 *M chimaera* infections have been reported after cardiothoracic procedures since 2013.⁵

In this issue of the *Journal*, Matte and colleagues⁶ report a rigorous approach to immediately address the risk associated with heater-cooler units. They converted water pipes running through a mechanical floor above the operating room into a closed water supply that can be temperature regulated and connected to the oxygenator heat exchanger unit of the heart-lung machine, thereby eliminating the commonly used heater-cooler systems. Most important, the new system does not vent exhaust into the operating room—the primary mode of transmission of NTM to the surgical field. Not every hospital may have the capacity and the suitable building structure to allow the implementation of such a fundamental change, but the described wall water system is certainly a thorough and efficient way to eliminate an identified source of mycobacteria.

The investigations triggered by early reports revealed that a contamination at a production site led to bacterial colonization of the LivaNova PLC (London, United Kingdom) (formerly Sorin Group Deutschland GmbH) Stöckert 3T Heater-Cooler System.^{5,7} Whole-genome sequencing and phylogenomic analysis provided strong evidence that this contamination was the source for *M chimaera* infections across the globe.^{5,8} However, it is likely that aerosolized transmission of NTM is associated with any heater-cooler device with an open water reservoir because the basic

modes of operation are the same.⁹ NTM contamination has been reported for many devices, even though a clear link between strains in a particular device and infections is lacking.⁹ The unspecific presentation of infections with NTM, the long latency period, and the particularly challenging detection add additional complexity. Therefore, the reported incidence of 0.1% to 1% can only be a rough approximation and is most likely underestimated. Until we get a better understanding of these infections, it is insufficient to assume that heater-cooler units are the source of infections in patients with cardiovascular disease undergoing open procedures only. Instead, it must be hypothesized that any device that is at risk of contamination with NTM and that allows contaminated water to aerosolize next to a patient susceptible to infection forms a potential source for infection. Therefore, removing these devices from the operating room is not eliminating the problem completely. Heater-cooler devices are commonly used in other areas, such as the intensive care unit and for patients on extracorporeal membrane oxygenation (ECMO). Pediatric patients on ECMO are often centrally cannulated and have an open chest for the time of mechanical support. If the patient shares a room with other patients, this may put not only the patient on ECMO but also every other patient in the room at risk of NTM infection. Concerns have also been raised for hybrid procedures in which the heater-cooler device is used for a backup cardiopulmonary bypass circuit, but the procedure itself is performed percutaneously.¹⁰ Therefore, instruments and implantable devices such as transcatheter

heart valves could become contaminated with NTM. This makes it difficult to identify patients at relevant risk on the one hand, and on the other hand to reliably trace NTM infections back to the source.

Matte and colleagues⁶ must be congratulated for going the extra mile to address heater-cooler–associated NTM infections. However, the authors report that Blanketroll III thermal regulating systems (Cincinnati Sub-Zero Products, Inc, Cincinnati, Ohio) are in use in their operating rooms. It seems possible that these patient blankets, fed from an open water reservoir and venting into the operating room, neutralize the effect of the wall water system.

We may not be able to completely eliminate heater-cooler devices from clinical practice. Therefore, it is even more important to follow manufacturer's instructions; to closely service, clean, and disinfect these devices; and to raise awareness of these infections among health care providers and patients. Clinicians and regulatory authorities should also increase the pressure on manufacturers to efficiently address this risk and to develop permanent solutions.

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