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Concise Communication

Successful termination of an outbreak of *Mycobacterium chimaera* infections associated with contaminated heater-cooler devices

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Abstract

The global outbreak of invasive *Mycobacterium chimaera* infections associated with heater-cooler devices (HCDs) presented several important and unique challenges. To mitigate the risk of infection, we removed the HCDs from operating rooms (ORs) at our hospital and since that time (4.5 years ago) we have had no new cases.

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Since 2011, when a Swiss patient was identified with disseminated *Mycobacterium chimaera* (a species in the *Mycobacterium avium* complex [MAC]) infection after cardiac surgery,[1] numerous such cases have been detected worldwide. These infections are associated with the production of *M. chimaera*–containing bioaerosols by the LivaNova (formerly Sorin) 3T heater-cooler device (HCD).[2,3] Investigators from Switzerland[2] and Germany[3] demonstrated that when HCDs are operating, *M. chimaera* can be detected in air samples and on settle plates in the operating room.[3] Initial investigations revealed that transmission of *M. chimaera* required a surgical wound and/or contamination of a prosthetic device on the sterile field,[1,2] no cases were associated with respiratory transmission, and there appeared to be no risk to healthcare personnel. Further epidemiologic investigation revealed that these HCDs were likely to have been contaminated at the manufacturing facility, where the water supply in the pump assembly area harbored *M. chimaera*.[4] Whole-genome sequencing (WGS) confirmed that this is a common source outbreak,[4] with nearly identical isolates found in LivaNova 3T HCDs and patients from Europe, United Kingdom, Australia, New Zealand, and the United States.[5] The risk of acquiring *M. chimaera* from a contaminated HCD is estimated to be 2.4 to 7.8 per 10,000 procedures.[6]

We reported a *M. chimaera* outbreak in our institution 4.5 years ago; here, we follow up on the effectiveness of the mitigation strategy that we implemented to successfully terminate it.[5] The approach adopted to reduce the risk of transmission was to separate the operative field from the HCD exhaust bioaerosol, and the most definitive option was to remove the HCD from the operating room. We accomplished this via construction of a 15.25 × 15.25-cm (6 × 6-inch) portal in the operating room wall covered by a sliding door to allow for passage of the HCD hoses through the wall to the HCD stationed outside the operating room.[5] The portal is not entirely blocked by the hoses; however, testing revealed that the room remained at positive pressure despite the small gaps. Determination of the site for the portal was guided by access to electrical power, maintaining proper corridor width per life safety code, and minimal interference with staff and equipment. These portals were constructed immediately after we became aware of our first case of HCD-associated *M. chimaera* infection in January 2016, and were fabricated of either Corian or stainless steel.[5] Another approach to bioaerosol containment used at some hospitals was construction of a custom-made stainless steel housing for the HCD to ensure separation between the exhaust air of the HCD and the operating-room air.[7]

The LivaNova 3T unit has been in use since 2006, and the earliest reported date of surgery associated with a case in the global outbreak was 2008.[1] The CDC recommended going back to January 1, 2012, for the purposes of notification, based upon the assumption that almost all cases developed manifestations of infection within 4 years.[5] We identified 7 healthcare-associated *M. chimaera* infections at our hospital after extensively investigating patients exposed to HCDs and individually contacting them via closed-loop communication (timeline shown in Fig. 1).[5] In addition, a retrospective review of laboratory records was performed to identify cultures growing MAC in specimens from blood, bone marrow, and other sterile sites, as well as wounds.

Another reason to remove the HCDs from the operating room is the resistance of this organism to disinfectants and the ability to form biofilm, which makes decontamination extremely difficult, if not impossible.[3,7] Other mitigation strategies that we employed with regard to maintenance and cleaning of the HCDs included following manufacturer's recommendations for HCD maintenance, including the use of sterile or filtered water, and regular water-circuit disinfection and tubing changes.[7] Contamination of brand new HCDs direct from the factory was quickly

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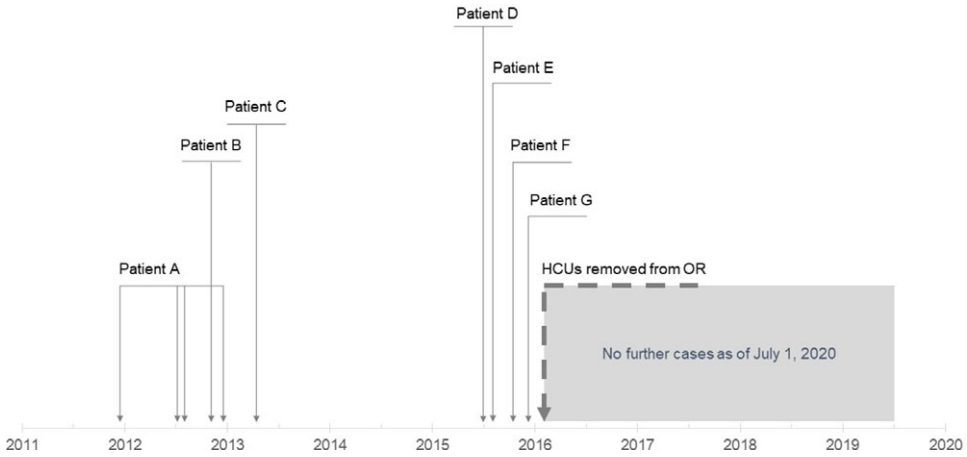

Fig. 1. Time line of surgeries among *M. chimaera* cases at the University of Iowa Hospitals and Clinics through July 1, 2020. Patient A had 4 procedures involving a heater-cooler device.

detectable,[4] and multiple cycles of decontamination failed to eliminate *M. chimaera* from HCDs[3] because a biofilm covering the walls and tubing remained.[3,4] When biofilm formation has occurred in an HCD, reprocessing the HCD can reduce but cannot remove it completely.[5,7] Some reports indicate that weekly water sampling for colony counts of *M. chimaera* is required indefinitely to monitor the water quality in these units as well as regular replacement of the tubing to control the build-up of biofilm.[8] Currently, only the 3T HCD has been clearly linked to *M. chimaera* infections of patients through contaminated aerosols.[5,8]

In a national survey of Canadian Nosocomial Infection Surveillance Program (CNISP) sites (n = 18), HCD testing and risk-mitigation strategies were diverse among respondents, whereas approaches to identifying and managing at-risk patients were similar.[9] LivaNova HDUs were used in nearly all surveyed sites (90%) and exclusively in the majority (65%). Only 4 sites (22%) sent their LivaNova HDUs back to the manufacturer for deep disinfection. In addition, half completed or were in the process of disinfecting their LivaNova HCDs locally. Other risk-mitigation strategies included replacement of device tubing at 10 sites (56%) and redirection of the exhaust in the operating room at 15 sites (83%). Only 1 site (6%) had moved the HCU outside the operating room, though this intervention was in progress at another site, and 3 sites (17%) were considering this approach.[9]

In a public health response to *Mycobacterium chimaera* contamination of HCDs and patient infections in Queensland, Australia, relocating HCDs outside of operating rooms was enacted in 1 of the 5 hospitals, with structural impediments preventing relocation in the remaining four. Custom-built boxes enclosing HCDs to protect the surgical field from aerosols were not utilized at any site.[10]

The International Society for Cardiovascular Infectious Diseases (ISCVID) recently recommended that facilities use other models of HCDs, or separate the HCDs from the operating-room air volume by placing them in dedicated utility rooms adjacent to the operating room, or place them in encasings with controlled air extraction via a duct to the operating room exhaust conduit.[8] However, products such as encasings that are engineered and built by hospitals may alter the function of the HCD and the potential for such changes in function should be taken into consideration when implementing such interventions. Removal of HCDs from the operating room may require reconfiguration of the design of the built environment.[5,8] If HCD exhaust air cannot be reliably separated from the operating room, HCDs should be placed as far as possible away from the operating field and the vent exhaust should be directed away from the patient and the surgical instruments.[5,8] Institutions should continue to follow updated manufacturer instructions for cleaning and disinfection of these devices.[5,8–10] However, there is no consistent evidence that *M. chimaera* can be eradicated from any HCD model once contaminated.

After removing HCDs from our operating rooms no further cases have been detected at our institution as of July 1, 2020. Our approach should be considered the most definitive option to eliminate the risk for infection due to bioaerosols, and we continue to recommend this strategy. Institutions that have not been able to separate the HCD bioaerosol from the operating room should maintain a high level of vigilance for the detection of new cases.

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