

Mycobacterial Infections Associated with Heater/Cooler Units in Cardiac Surgery - European Perspective

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Learning Objectives: Participants will learn about the impact of the heater-cooler crisis in Europe and the steps taken by national and international regulatory bodies

In 2013, Achermann et al. described the first 2 cases of endocarditis with *Mycobacterium Chimaera*, with fatal outcome, occurring late after the placement of a valve prosthesis under CBP. (1)

More studies were undertaken and multiple reports of endocarditis in different countries with similar pathogen were identified across Europe, fortunately not all with fatal outcome. It was established that the heater cooler units (HCU) and the air surrounding the HCU's were contaminated with *M. Chimaera*.

In Belgium, the Federal Agency for Medicine and Health Products issues a warning in August 2014 and starts collecting data on the number of HCU's in use and possible infections associated with *M. Chimaera*. Only after reminders in November 2015 and February 2016, some information could be obtained.

Meanwhile, in October 2015, the FDA issues recommendations to minimize patient exposure (2) and the European Center for Disease Control (ECDC) issues a Rapid Risk Assessment in April 2015, warning that since 2011 (!), there is an increased risk of *M. Chimaera* infection for patients undergoing open heart surgery and that there is an association between the infections and the contaminations of HCU's.

Different countries (Switzerland, UK, Germany, Netherlands, Belgium) and the ECDC have since then issued publications regarding measures to be taken to protect the patients from this potential infectious risk. Extensive protocols regarding the way HCU's should be sampled, tested, maintained, cleaned or disinfected are described.

References

1. Achermann Y, Rossle M, Hoffmann M, Deggim V, Kuster S, Zimmermann DR, et al. Prosthetic valve endocarditis and bloodstream infection due to *Mycobacterium chimaera*. *J Clin Microbiol* 2013;51(6):1769-73.
2. Nontuberculous *Mycobacterium* Infections Associated with Heater-Cooler Devices: FDA Safety Communication
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm466963.htm>
3. CDC – Center for Disease Control and Prevention. Non-tuberculous *Mycobacterium* (NTM) Infections and Heater-Cooler Devices Interim Practical Guidance; 2015. Internet: <http://www.cdc.gov/HAI/pdfs/outbreaks/CDC-Notice-Heater-Cooler-Units-final-clean.pdf>