

## Frequently Asked Questions for Hospitals Notifying Patients of Risk from Contaminated Heater-Cooler Devices Used During Cardiac Surgery

**Q. How far back in time should hospitals go to notify patients?**

**A.** Hospitals should consider notifying patients **in writing** if they were exposed to the Stöckert 3T devices during open-chest cardiac surgery at their institution since **January 1, 2012**. Hospitals that did not use the Stöckert 3T device during this entire time period should adjust the patient notification timeframe accordingly.

**Q. What is the rationale for active patient outreach? Why use this time frame?**

**A.** Based on our current understanding, the majority of patients who become infected from exposure to these devices will develop symptoms within months of their exposure. Pursuing active patient outreach using a longer time frame of approximately 4 years is expected to benefit most of the patients who have developed symptoms but have not yet been diagnosed. However, any patient who has had cardiac surgery with the Stöckert 3T device – including patients who had their surgery prior to 2012 – should be aware of this risk in the event that they develop concerning symptoms. Other forms of patient outreach (e.g., through advocacy channels or the media) will be helpful in this regard. Likewise, ongoing efforts to raise awareness among clinicians is expected to benefit all patients, regardless of when their exposure occurred.

**Q. Our hospital acquired a Stöckert 3T device after September 2014. Should we still notify patients?**

**A.** Patients who were exposed to Stöckert 3T devices manufactured after September 2014 should also be notified. While the risks associated with these newer devices may be lower, some have tested positive for *M. chimaera* (see [FDA Safety Alert](#)), possibly as a result of cross contamination from accessory devices.

**Q. Our hospital conducted retrospective case-finding and we did not identify any probable cases – do we still need to send patient letters?**

**A.** Yes, while case finding is important, negative results cannot be relied upon to determine an absence of risk.

**Q. Our hospital conducted retrospective case-finding and we identified a probable case that had surgery before January 1, 2012. Do we need to extend the time period of our notification?**

**A.** Decisions to extend notification farther back in time using individualized patient letters may best be considered on an institution-specific basis. The likelihood of identifying undetected infections diminishes with time. However, directly notifying individual patients who have been identified as having actually acquired an infection from a contaminated heater cooler device is advisable regardless of when the exposure occurred.

**Q. Are only patients who have had prosthetic material implanted during their cardiac surgery at risk for *M. chimaera* infections? Should our hospital only notify patients who have had prosthetic material implanted?**

**A.** Although there is some evidence that patients who have prosthetic material implanted during their open-chest cardiac procedure may be at higher risk of developing infection, heater-cooler device associated NTM infections have also occurred among patients who did not have placement of prosthetic material. Therefore, hospitals should not determine which patients to notify based on whether they have had the placement of prosthetic material during their procedures.

**Q. In 2015, our hospital took measures to mitigate risk to patients by following updated manufacturer's recommendations for disinfection and cleaning and updated guidance from the FDA. Do we still need to notify patients?**

A. Yes, hospitals should still notify patients. A possible exception pertains to hospitals that have taken additional steps (e.g., moved the Stöckert 3T device out of the operating room) to eliminate patient exposure to the exhaust from these devices. These hospitals may consider not notifying patients who had surgery after these interventions if they are confident that the risk was abated.

**Q. The Stöckert 3T device(s) at our hospital tested negative for *M. chimaera*. Should we still notify patients?**

A. Yes, hospitals should still notify patients. In general, methods for sampling and microbiological testing of heater-cooler devices for *M. chimaera* are neither reliable nor timely. Therefore, negative test results do not necessarily indicate that devices are not presently contaminated or that they have not been contaminated in the past.

**Q. How do I diagnose a patient with *M. chimaera* infection? How do I treat a patient with an *M. chimaera* infection?**

A. Initial experience from clinicians indicates that these infections can be challenging to diagnose and treat. **Patients have presented with a variety of clinical manifestations including endocarditis, surgical site infection, or abscess and bacteremia. Other clinical manifestations have included hepatitis, renal insufficiency, splenomegaly, pancytopenia, and osteomyelitis. Patients have also presented with granulomatous disease and have been misdiagnosed with sarcoidosis.** CDC recommends that physicians consult with an infectious disease specialist for specific clinical concerns regarding these infections. CDC hosted a webinar on August 29th which included a presentation by clinical experts on the diagnosis and treatment of *M. chimaera* infections. The recorded webinar can be found here: <https://www.youtube.com/watch?v=zPSLD3Um0sw>