

November 7, 2016

Dear Healthcare Provider,

Arnold Palmer Hospital for Children (APH) is notifying referring providers of recent findings from the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) regarding patients who have undergone open-chest cardiac surgery using a specific heater-cooler device, the LivaNova PLC Stockert 3T Heater-Cooler. The devices have recently been linked to a rare bacterial infection caused by *Mycobacterium chimaera*, a slow-growing species of nontuberculous mycobacteria (NTM). Investigations into several clusters of infections linked to exposures to this device during cardiac bypass surgery have determined that these devices were likely contaminated with *M. chimaera* during manufacturing.

Patients with NTM infections following cardiac surgery have presented with a variety of clinical manifestations. Common examples include endocarditis, surgical site infection, or abscess and bacteremia. Other clinical manifestations have included hepatitis, renal insufficiency, splenomegaly, pancytopenia, and osteomyelitis. **Arnold Palmer Hospital has not identified any of these infections in our patients.**

*Mycobacterium chimaera* is slow-growing and patients may not experience symptoms for months or even years after surgery. Clinicians and patients may not immediately consider an NTM infection when symptoms present. Delayed diagnosis may make treating these infections more challenging. There is no test to determine whether a person has been exposed to the bacteria. Infections can be diagnosed by detecting the bacteria by laboratory culture, however the slow growing nature of the bacteria can require up to two months for test results that can rule out infection.

We are currently in the process of notifying our patients and families that may have been impacted. APH has consistently adhered to the stringent cleaning, disinfection and maintenance of the devices according to revised manufacturer's guidelines and have found no evidence of NTM infections in patients who have undergone cardiac bypass surgery. The chance of getting an NTM infection is very low; in hospitals where at least one (1) infection has been identified, the CDC estimates the risk of infection to be between 1 in 100 and 1 in 1000.

CDC is recommending that clinicians, including cardiologists and general practitioners who take care of cardiac surgery patients before and after their surgery, be aware of the risk and **consider NTM as a potential cause of unexplained chronic illness.** Symptoms of an NTM infection may include:

- unexplained fever
- redness, heat, or pus around a surgical incision
- night sweats
- muscle aches
- weight loss
- fatigue

When seeing patients with possible NTM infections and a history of cardiac surgery, clinicians should consider arranging consultation with an infectious disease specialist. If an NTM infection is suspected, it is important to obtain acid fast bacilli (AFB) cultures from an infected wound and/or blood to increase the

likelihood of identification of the organism and to obtain an AFB smear in order to have preliminary information while awaiting culture results.

For more information, please refer to the website links below. If you wish to speak with a member of the APH cardiac team, please call 321-843-7200. You will be prompted to leave a message and someone will return your call as soon as possible. For clinical questions about NTM infections, please consider an infectious disease consult.

<https://www.cdc.gov/HAI/outbreaks/heater-cooler.html>

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm>

<http://www.arnoldpalmerhospital.com/pediatric-specialties/pediatric-cardiology-and-cardiac-surgery>

Sincerely,

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Arnold Palmer Hospital for Children