

SAMPLE PRIMARY HEALTHCARE PROVIDER NOTIFICATION LETTER

Dear Healthcare Provider:

[HEALTHCARE FACILITY] is notifying providers of recent findings from Centers for Disease Control and Prevention (CDC), in collaboration with National Jewish Health, regarding patients who have undergone open-chest cardiac surgery. Heater-cooler devices used during certain major surgeries that require the use of a heart/lung bypass machine 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 LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stöckert 3T heater-cooler devices during cardiac bypass surgery have determined that these devices were likely contaminated with *M. chimaera* during manufacturing.

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:

- night sweats
- muscle aches
- weight loss
- fatigue
- unexplained fever

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. Patients have also presented with granulomatous disease which can imitate sarcoidosis.

M. chimaera are 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 even 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; the slow growing nature of the bacteria can require up to two months to rule out infection.

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.

In our letter to patients, we encourage them to discuss any symptoms with their primary care physician or to call _____ if they have any questions or concerns.

If you have a clinical question pertaining to one of your patients, or if you have a symptomatic patient who requires additional evaluation for potential NTM infection, please call _____ and speak to _____.

We are working with the _____ Department of Health to guide our response, and will continue to partner with CDC and FDA to ensure we are following all safety recommendations. We believe that with our current practices we can continue to provide patients who need this device with safe, high-quality care.

If you have any questions about talking to your patients or anything else regarding this infection, please do not hesitate to contact us.

Sincerely,

NAME

TITLE

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