

December 10, 2020

Dr. Jane Doe
115 Happy Lane
Joyville, USA 111223

Re: Patient <Mary Smith>, DOB <XX/XX/XXXX>

Dear Dr. Doe:

Beth Israel Deaconess Medical Center is notifying referring providers of recent findings of a few infections of *Mycobacterium abscessus*, a type of bacteria known as nontuberculous mycobacterium (NTM), among patients who underwent open-heart surgery between February and March 2020.

Our records show that your patient, Mary Smith, underwent surgery at BIDMC during that timeframe. Although the risk of infection is very low, we are contacting you as a precaution to inform you about this development.

An extensive investigation has been completed, and the infection is thought to be associated with the CardioQuip Modular Cooler-Heater Device -- a device used by hospitals across the nation during certain cardiopulmonary bypass procedures. An international outbreak of another type of NTM was reported with a different brand of these devices in 2015. Infection with NTM is rarely seen following cardiac surgery procedures.

BIDMC has been partnering with the Massachusetts Department of Public Health, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) in this investigation. The FDA recently issued a Letter to Health Care Providers about this event to alert other clinicians to potential risks in their facilities.

The FDA 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. *M. abscessus* are slow-growing bacteria and infections generally occur within the first one to two months after surgery. However, in rare cases, infections may take months or even years to cause symptoms. Symptoms of an invasive 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.

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. If you have a symptomatic patient who may require additional evaluation for potential NTM infection, please consider arranging for evaluation in the BIDMC Infectious Disease clinic. To schedule an appointment, please call the clinic at (617) 632-7706.

In our letter to patients, we encourage them to discuss any symptoms with their primary care physician and/or to call our NTM hotline at (617) 975-9770. The hotline is staffed by our Patient Relations team. If you have any questions about how to talk to your patients about the potential infection risk, please contact the NTM hotline at (617) 975-9770. You can also find more information on our website at <https://www.bidmc.org/cardiacrisk> and on the CDC and FDA websites:

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

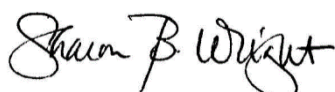
FDA: <https://www.fda.gov/medical-devices/letters-health-care-providers/potential-risk-infection-during-cardiac-surgery-when-using-cardioquip-modular-cooler-heater-device>

We are working with the Massachusetts Department of Health to guide our response. We will continue to partner with CDC and FDA to ensure we are following all safety recommendations and will notify you of any changes in our current management plan.

Sincerely,



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Director, Health Care Quality



Sharon B. Wright MD, MPH
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Anthony P. Weiss, MD, MBA, MSc
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