Penn Medicine
Penn Presbyterian Medical Center
Administration

September 19, 2016

Dear Provider

As one of our valued partners in caring for patients requiring cardiac surgery, we are writing to alert you about the steps we have taken to address a device-related issue that has been affecting cardiac surgery programs across the country and in Europe.

As you may be aware, the U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) have notified hospitals about a bacterial contaminant that has been identified in the water reservoir of certain heater-cooler devices used in conjunction with the cardiopulmonary bypass machines during cardiac surgeries. These agencies have advised that when the bacteria become aerosolized during use of the heater-cooler devices, surgical site contamination can occur which may result in infection. The specific bacterium identified by the CDC is Mycobacterium chimaera, a Nontuberculous Mycobacterium (NTM) which is commonly found in the environment. The CDC estimates that the risk of infection is less than one percent.

Recently, we became aware that four patients who had cardiac surgeries involving the use of cardiopulmonary bypass performed at our hospital between October 1, 2013 and December 17, 2015 had been diagnosed with a NTM infection. Although we believe that it is very unlikely that one of your patients whom you may be following after cardiac surgery will develop this infection, we nonetheless wanted to alert you about this development.

The most common symptoms of NTM are those associated with an unexplained infection. These include fever of undetermined origin, night sweats, and unexplained weight loss. Patients who have developed NTM infections post cardiac surgery have presented with a variety of clinical manifestations including endocarditis, cardiac surgical site infection and bacteremia as well as hepatitis, splenomegaly and osteomyelitis. As NTM is a slow-growing bacterium, it can take from several months to several years for symptoms to develop. It therefore is recommended that NTM be included in the differential diagnosis for any unexplained infections in these patients for up to four years.

Consistent with our commitment to patient safety, we always have strictly adhered to manufacturer guidelines for disinfecting and maintaining these heater-cooler devices. After the CDC issued its advisory with recommendations for more stringent disinfection practices, we immediately implemented those recommendations and went beyond what the CDC recommended. Although these infections are rare, we replaced all of our heater-cooler devices from the manufacturer that was the focus of the FDA's investigation with heater-cooler devices from another manufacturer to address this potential risk.

In response to the recently identified cases, in consultation with the CDC and the state Department of Health, we have taken the following steps:

- We have identified all patients who underwent cardiac surgery utilizing cardiopulmonary bypass between October 1, 2013 and December 17, 2015. The inclusive dates reflect the period during which we were using the heater-cooler units at issue.

- We are sending letters to these patients to inform them of the issue identified with the heater-cooler units, to explain the associated risk, the symptoms for which they should seek medical evaluation, and to provide them with additional information. We likewise have posted resource material on our website: https://www.pennmedicine.org/ppmc-cardiac-bypass. If any of your patients receive this letter, they may contact you or provide you with a copy of this letter.

- We have set up a dedicated toll-free telephone line staffed by registered nurses who will answer questions, administer a brief screening survey and, if indicated, assist patients who may need medical evaluation with scheduling an appointment with one of our providers at no cost to them.

If you have any questions or concerns or if we can provide any assistance to you or one of your patients, please call the toll-free hotline: 1-800-890-6963, identify yourself as a provider and you will be routed to the appropriate provider for a return call. Thank you for partnering with us to ensure the continued health and well-being of our mutual patients.

Sincerely,

Michele M. Volpe
Chief Executive Officer

Kevin M. Fosnocht, M.D.
Chief Medical Officer