

December 07, 2015

In follow up to our first letter from Nov. 10, we are writing to update you about our recommendations related to patients who had a specific type of cardiac surgery at Penn State Milton S. Hershey Medical Center in the past four years. As a reminder, the concern is related to a rare bacterial infection caused by non-tuberculous mycobacterium (NTM) that federal agencies believe is connected to a type of device—a heater-cooler—that is used throughout the country. Out of approximately 2,300 patients, we have confirmed three cases in which a patient developed this infection after open-chest, cardiac surgery performed between Nov. 5, 2011 and Nov. 5, 2015.

As we move forward, we plan to risk-stratify patients to determine the type of follow-up that is most appropriate for the potentially exposed patients. We developed this plan based on reports about NTM infection from the literature, consensus opinion of our Infectious Diseases physicians and communication with a European investigator experienced in treating similarly situated patients abroad. There are no current published guidelines on screening patients potentially exposed to NTM but who are asymptomatic.

Patients with NTM infections following cardiac surgery have presented with a variety of clinical manifestations. Common examples include endocarditis, surgical site infection, and bacteremia. However, other clinical manifestations have included hepatitis, splenomegaly and osteomyelitis. These infections have been diagnosed across a wide time frame - within a few weeks to as long as 3 ½ years following the procedure.

To date, the overall risk for development of disease is very low, but patients known to have developed NTM infection following cardiac surgery have undergone heart transplantation, valve reconstruction or implantation of foreign material. The latter group includes prosthetic valves (tissue or mechanical), vascular grafts and devices such as left ventricular assist and total artificial heart devices. There are currently no reports of invasive NTM infection in patients who have undergone less complex cardiac procedures without placement of foreign material. The development of infection may be related to implantation of foreign material, but it also could be related to the generally long duration of cardiopulmonary bypass with these types of procedures. The risk factors have not been carefully studied thus far. However, approximately 1,200 of the total patient group potentially exposed during surgery at Penn State Hershey (approximately 2,300) underwent heart transplantation, valve reconstruction or implantation of foreign material over the four-year time frame.

(OVER PLEASE)

We are making arrangements to evaluate these 1,200 patients at Penn State Hershey. The adults will be screened by trained advanced practice clinicians, and the children will be screened by pediatric cardiology providers using symptom, physical exam and laboratory criteria (see Table 1 below) as appropriate. We do not endorse routine screening imaging studies at this point.

The patients will be referred for further evaluation to one of our Infectious Diseases providers if there is concern after review of the clinical screening results. If there is continued concern for NTM infection based on the Infectious Diseases assessment, further testing or treatment will be offered. If the screening evaluation is negative, we ask that you continue to monitor your patient for the symptoms and signs listed below. We will send a follow-up communication at a later date recommending frequency of screening evaluations for this group of patients. If your patient does not wish to be evaluated at Penn State Hershey Medical Center, or if you have questions about this screening process, please feel free to call our toll-free, 24-hour line, 1-877-467-7484, between 8:30 a.m. and 5 p.m. and request to speak with an Infectious Diseases physician.

Based on limited available information, the remaining 1,100 patients are believed to be at lower risk of developing NTM infection. We recommend you follow these patients for the development of symptoms and signs of infection and remain guided by the CDC's Interim Practical Guidance on this issue. In addition, these patients should call the 24-hour toll-free line (1-877-467-7484) if they have any questions or concerns regarding their condition. A nurse will be available to address their questions and also will screen them for symptoms. If there is concern by the nurse based on the screening responses, or if an asymptomatic patient in this group expresses a desire to be evaluated, we will arrange for the patient to be seen following the same process outlined above.

As our evaluation progresses and we learn more about these patient populations, we will continue to evaluate our recommendations concerning patient follow up. We will keep you advised of any changes to our recommendations.

Again, we do not recommend antibiotic prophylaxis in this situation. We also emphasize that patients who had other, less invasive heart procedures – such as stents, pacemakers, defibrillators and ablations – or minimally invasive cardiac surgery procedures – such as transcatheter aortic valve replacement, or TAVR – are not at risk and they do not require this screening.

This is not tuberculosis, and sputum cultures are of no value in these evaluations.

We will not charge patients for the cost of assessments or the tests ordered and provided by our providers or at our facilities to screen for NTM infection. If patients are unable or unwilling to receive these services from us, we will work with them to coordinate the necessary tests with their local providers. In those cases, we will reimburse providers for reasonable charges for tests and other services we have pre-approved.

We are sending letters to both subgroups of our potentially affected patient population to help reassure them and encourage them to call us to discuss follow-up we may recommend based on the specific cardiac procedure they had done. We expect those letters to start reaching patients just after the Thanksgiving holiday. Should you hear from any of your patients about this matter in the meantime, you may direct them for more information to our toll-free line, 1-877-467-7484.

We encourage you to call the toll-free line if you have further questions or concerns, or if you need additional guidance.

Sincerely,

Alan L. Brechbill
Executive Director
Milton S. Hershey Medical Center

Carol V. Freer, MD, FACP
Associate Professor of Medicine
Chief Medical Officer

Symptoms	Physical examination	Laboratory testing
Fevers	Vital signs	CBC, differential, platelets
Night sweats	Heart exam	CRP
Chills/rigors	Lung exam	ESR
Weight loss	Abdomen exam (liver/spleen)	Comprehensive metabolic panel
Fatigue/malaise	Lymph nodes	LDH
Failure to thrive	Examine for peripheral stigmata of endocarditis	Mycobacterial blood culture
Incisional drainage or redness		

*Additional studies may be indicated if patient is symptomatic or depending on exam and laboratory results.

Readings:

Penn State Hershey Medical Center website (contains additional resources including frequently asked questions): <http://www.pennstatehershey.org/open-heart>

Kohler P. *et al.* Healthcare-associated prosthetic heart valve, aortic vascular graft, and disseminated Mycobacterium chimaera infections subsequent to open heart surgery. *European Heart Journal*. 36:2745-53. 2015.

CDC Interim Practical Guidance. Non-tuberculous mycobacterium (NTM) infections and heater-cooler devices. Department of Health and Human Services, Centers for Disease Control and Prevention. October 27, 2015.