

**ATTENTION: Important Update on Caring for Patients Potentially Exposed to NTM**  
***Please share this with your physicians & advanced practice clinicians***

December 7, 2015

Dear Physician or Advanced Practice Clinician,

I am writing in follow up to our communication to you earlier this month to update you about recommendations related to patients who had a specific type of cardiac surgery at WellSpan York Hospital in the past four years.

Our primary consideration has been the support of those patients who were potentially exposed to non-tuberculous mycobacterium (NTM) and are considered to be at risk of infection from this organism, based on guidance from the Pennsylvania Department of Health (DoH) and the U.S. Centers for Disease Control and Prevention (CDC). As a reminder, the concern is connected to a type of device—heater-cooler—that is used throughout the country during open-heart surgery. We have notified approximately 1,300 open-heart surgery patients of possible exposure to NTM during open-heart procedures performed between Oct. 1, 2011 and July 24, 2015.

This letter is to inform you that we are enhancing our support system for these patients. In addition to our dedicated nurse case managers, who have already begun to serve as a health care resource for patients who need additional care or treatment related to this issue, we have also had dozens of referral patients for more detailed follow-up evaluation by a physician or advanced practice clinician in our Infectious Disease practice. We have found this to be a patient-centered support structure, and the feedback we have received from patients to date has been positive.

**What's New?**

We are now expanding this service by providing patients with a special, dedicated NTM clinic that will not only accept referrals, but will also do proactive outreach to a specific subset of these 1,300 patients who could have a higher likelihood of acquiring this infection. This NTM clinic, which be located on WellSpan's Apple Hill Campus in York, will be open in mid-December and will be available for as long as it is needed. The clinics will be staffed by dedicated advanced practice clinicians, with support from the physicians of WellSpan Infectious Disease Specialists, who will provide routine, ongoing evaluation for this subset of patients (Please see details below and the attached algorithm of patient and physician support). We started this effort because it was the right thing to do for our patients, and we will continue to build on these efforts – and evolve them – as our patients' needs require.

We remain fully committed to ensuring that our patients have all the information, care and treatment that they require regarding this issue. We continue to assess this situation and evaluate the best way to address these concerns and needs. We also continue to collaborate and closely coordinate with our colleagues from the Penn State Milton S. Hershey Medical Center in attempt to understand the nature of these infections and provide prompt detection and treatment. In doing so, we are sharing our knowledge and modifying our recommendations as we gain additional experience with this rare and unusual infection.

**Penn State Hershey Collaboration**

As you may know, on Nov. 10, 2015, Penn State Hershey Medical Center announced that it had confirmed three NTM infection cases out of approximately 2,300 patients who may have been exposed to the bacteria during open-chest cardiac surgery performed between Nov. 5, 2011 and Nov. 5, 2015 at that hospital. In response, the medical center is now monitoring its 2,300 potentially exposed patients.

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WellSpan York Hospital and Penn State Hershey Medical Center have worked closely over the past two weeks to understand the risks to our potentially exposed patients. We have been in ongoing communication with the CDC and DoH. In addition, Penn State Hershey has been in 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. As this clinical situation evolves, we will keep you apprised of any updates in recommendations.

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 months to as long as 3 ½ years following the procedure.

To date, the overall risk for development of this infection is very low. Currently, less than 1 percent of patients who had open-heart surgery at WellSpan York Hospital during this four-year timeframe have acquired this infection. However, we understand that even this low risk can cause high anxiety among some patients. We also know the risk factors associated with this infection have not been carefully studied thus far, presenting a challenge in monitoring patients for possible signs of infection.

That said, in consultation with our colleagues at Penn State Hershey Medical Center, it is our joint clinical opinion that there may be a subset of patients who could have a higher likelihood of acquiring this infection. This is a rapidly developing situation, and our recommendations may change in the future. In the interim, however, we believe that patients who have had implantation of foreign material may have a higher likelihood for infection than those who did not have these types of procedures. Patients who may be more likely to acquire the infection are those that had the following procedures: prosthetic valves (tissue or mechanical), vascular grafts and left ventricular assist devices.

### **Specialized Support Clinics Offered**

Although the risk for developing an infection remains extremely low, we want to make it as easy as possible for our patients to exercise precaution and to monitor any symptoms that could be associated with a possible NTM infection. We also want to do all we can do minimize their anxiety.

For these reasons, both WellSpan York Hospital and Penn State Hershey Medical Center plan to operate specialized clinics that will focus on those specific patients who have had these types of procedures. Penn State Hershey has identified more than 1,200 patients (of the total of 2,300 potentially exposed patients), and WellSpan York Hospital has identified 383 similar patients (of the total of approximately 1,300 potentially exposed patients) who may have a higher likelihood of infection. WellSpan and Penn State Hershey will each notify their respective patients and offer them in-office evaluations, which will include documenting clinical history, conducting a focused physical examination, and, if clinically appropriate, providing laboratory testing. We have determined that this clinic is an important resource that can, and will, be made available to patients who need it for the foreseeable future. We will continue to collaborate with Penn State Hershey to determine together the best model of personalized care and treatment for these patients.

Although any patient who underwent open heart surgery at WellSpan York Hospital between Oct. 1, 2011 and Jul 24, 2015 may schedule an appointment at the clinic to undergo an evaluation and discuss appropriate lab testing, this clinic is intended to serve individuals who had one of the following procedures: placement of left ventricular assist devices (LVADs), placement of artificial heart valves or vascular grafts.

We recommend that patients who had these procedures schedule an appointment at our clinic at the Apple Hill Campus, and we will be contacting these patients within the next month to begin scheduling appointments. Patients experiencing unusual symptoms such as fever, night sweats or weight loss that have not been explained by any other illness, should schedule an appointment as soon as possible. We will notify patients' primary care physicians when these patients have been seen and will also notify their PCP of the results of the evaluation.

We will follow-up with the 1,300 patients who underwent open heart surgery at WellSpan York Hospital during this four-year time period via letter to inform them of this clinic and to encourage them to contact us to discuss appropriate follow-up that we may recommend based on the specific cardiac procedure they had done. If patients contact you with any questions about this issue, or they want to schedule an appointment at the clinic, please have them call our toll-free Nurse Case Manager Call Center at 866-217-2970.

### **Continued Patient Monitoring Recommended**

We are advising open-heart patients, who did not undergo one of the specific procedures mentioned above, to continue to follow-up with their primary care physician. For these patients who are considered less likely to develop this infection, there are no suggested screening protocols, and we caution against ordering any tests in asymptomatic patients. Even so, you should have a higher index of suspicion for any infections that do not resolve with regular treatment. If you care for one of these patients in the inpatient setting and you are concerned that the patient's symptoms could be related to NTM infection, then please call 717-812-4933 for further consultation with WellSpan Infectious Disease Specialists. However, if the admission is completely unrelated to an infectious process, please do not order NTM testing or seek an Infectious Disease consultation.

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 – are not considered to be at risk for NTM infection associated with heater-cooler devices and therefore do not require screening.

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.

If you have a clinical question pertaining to one of your patients, or if you have a patient who requires additional evaluation for potential exposure to this bacteria, please call 717-812-4933. You will be connected to a physician assistant who is working with Eugene M. Curley III, M.D., and his team of clinicians at WellSpan Infectious Disease Specialists, to answer your questions and expedite care. Additional resources are also available on our public website at [www.WellSpan.org/YorkOpenHeart](http://www.WellSpan.org/YorkOpenHeart).

Again, we sincerely appreciate your tremendous efforts on behalf of our patients and the collaborative spirit with which you have engaged with us.

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Sincerely,



Charles M. Chodroff, MD  
Senior Vice President, Population Health, and Chief Clinical Officer  
WellSpan Health