

December 04, 2015

We are writing because you or a member of your family underwent a specific type of heart surgery at Penn State Milton S. Hershey Medical Center between Nov. 5, 2011 and Nov. 5, 2015. We would like to update you following our previous letter of Nov. 13, 2015 and to advise you of follow-up recommendations we have developed.

You may recall that in our first letter, we alerted you to the fact that we had identified three Medical Center patients (out of more than 2,300), who had developed a rare bacterial infection caused by non-tuberculous mycobacterium (NTM) after undergoing heart surgery with an open chest. Federal agencies believe that these infections may be related to a device called a heater-cooler that is used throughout the country during open-chest heart surgeries. Based on our experience to date and reports in the medical literature, we believe that the potential of you having an infection is low, with about one-tenth of 1 percent of our patients having been diagnosed with this infection.

We want to assure you that we continue to follow this issue and are taking precautionary steps to ensure appropriate follow-up and care. Out of concern for our patients, we have set up a dedicated clinic where we can answer your questions, examine you and perform appropriate lab tests if needed.

To date, patients known to have developed an invasive NTM infection following heart surgery with an open chest at our hospital and other hospitals in the country and in Europe have undergone complex procedures like heart transplantation, heart valve reconstruction or surgeries involving the implantation of foreign material. This includes patients who have undergone surgeries for:

- tissue or mechanical heart valves,
- vascular grafts,
- left ventricular assist devices (LVADs), or
- total artificial heart devices.

(OVER PLEASE)

We strongly recommend that patients who have undergone any of these surgeries between Nov. 5, 2011 and Nov. 5, 2015 call our 24-hour toll-free line (1-877-467-7484) to schedule an appointment to be evaluated in our dedicated clinic. We expect to see all patients who have had the procedures mentioned above and who wish to be seen related to this matter within the next 2-3 months. We will not charge patients for the cost of clinic evaluations or tests that may be ordered and performed by our providers or at our facilities to screen for NTM infection.

Importantly, we are unaware that any patients have developed invasive NTM infections after undergoing less complex heart surgeries with an open chest but without placement of any foreign material, as listed above. For this reason, we recommend that you or your loved one who may have had this type of surgery continue to be followed by your primary care provider. We are asking these providers to monitor their patients for any future concerns. If you cannot reach your provider or do not have a provider who has been involved with your heart care, please contact our toll-free line for further information. Additionally, we understand that even if you are in this group of patients, you may be concerned and may also want to be evaluated in our dedicated clinic. Please call our toll-free line and we will be happy to schedule you to be seen.

If you are unsure what type of procedure you or your family member had at the Medical Center, please call us at 1-877-467-7484. If you are calling on behalf of your child, your call will be referred to the Children's Heart Group, who will make arrangements to evaluate your child at a pediatric practice site that is convenient to you.

Most patients will not experience an infection from this possible exposure. If you are having symptoms such as fever; pain, redness, heat, or pus around a surgical incision; night sweats; joint pain; muscle pain; fatigue; or, weight loss that have not been explained by any other illness, we urge you to contact your provider or call our toll-free line.

We have sent a follow-up letter to our Penn State Hershey providers and to non-Penn State Hershey providers, so your provider should be aware of our plans and how to reach our Infectious Disease specialists for consultation if needed. We will also continue to keep you informed about this matter as we learn more information.

Additional information is also available on our website: <http://www.pennstatehershey.org/open-heart>.

We sincerely regret any distress that this matter may create for you and your family. Please know we are fully committed to ensuring that you have all the information, care and treatment that you require regarding this matter.

The safety and well-being of our patients is our highest priority. We remain committed to providing you with exceptional care.

Sincerely,

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

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