Bacterial infection tied to heart surgery device

Debra Erdley

At 74, Bob Marks is grateful to be alive after collapsing at his Hempfield home last summer with an aortic dissection, a tear in the wall of the major artery carrying blood out of his heart.

Marks, a retired Lutheran pastor and registered nurse, said he's thankful for the flight team that got him to the hospital and the surgeons who saved his life at Allegheny General Hospital.

But he's begun to wonder whether the myriad complications that plagued his recovery — fatigue, night sweats, pneumonia, influenza and shingles — could be related to a rare form of bacteria called non-tuberculous mycobacterium, or NTM, found in heater-cooler devices used in open-heart surgery in about 60 percent of U.S. hospitals. The devices in question are known as Stockert 3T units.

NTM is common in water and soil, and the bacteria can trigger a rare infection if it lands on immune-compromised individuals whose chests are open during cardiac surgery.

The FDA said it received 79 reports of patient infections, including 12 deaths worldwide, associated with the Stockert 3T heater-cooler system between January 2010 and August 2016.

But experts say the potential for problems from the slow-growing infection — NTM can take from several months to several years to develop — is significant in this country, where 250,000 open-heart procedures are

performed each year.

Allegheny Health Network, which used the 3T devices in open-heart surgeries at Allegheny General and West Penn hospitals between Aug. 29, 2012, and March 14, 2017, began notifying patients such as Marks of the potential problem this year.

In a letter dated July 5, Allegheny Health Network advised Marks of the potential for NTM, saying, “The chances of developing this infection are very low, and the (U.S. Centers for Disease Control and Prevention) estimates the risk to be less than 1 percent.”

The letter said AHN was not aware of any patients who had developed the infection. Nonetheless, Marks, who had worked as an infection control nurse at a large group home and was a member of the local infection control board, began checking off his complications against those known to come from NTM.

“Whether cause and effect is valid, or whether I was just worn out and susceptible, I don't know. But this helps me put the pieces together,” Marks said.

He is a lifelong asthmatic and won't undergo evaluation for possible issues related to the device until Aug. 31. Nonetheless, Marks is exploring legal action against the European manufacturer of the 3T heater-cooler units.

“I don't expect this to be a cash cow. And I would never sue the doctor or the hospital. They saved my life. But if my experience can help someone else, that's important to me,” Marks said.

Tracking the source

The case linking the rare infection to a specific device has been emerging for

years in a medical detective saga spanning three continents.

Experts now believe NTM finds its way into operating suites when water in an internal tank in the device becomes contaminated. Although the water never comes into direct contact with patients, droplets can work their way into the internal workings of the device, be picked up by a fan, dispersed into the air and land on the patient undergoing surgery.

The trail that culminated in the latest warnings began with anecdotal reports of the rare infection out of Western Europe about a decade ago. In 2015, WellSpan York Hospital in Eastern Pennsylvania became the first U.S. hospital to identify such infections among patients who had undergone open-heart surgery there.

A 2015 study in Switzerland triggered warnings across Europe. And the CDC issued an alert on Oct. 13, 2016, advising U.S. hospitals that used the device to alert patients to the potential for NTM.

Things reached critical mass this year with the release of a new study from the Special Pathogens Laboratory in Pittsburgh that found NTM in 33 of 89 units from 23 hospitals in 14 states; Washington, D.C.; and Canada sampled from July 2015 through March 2017. The lab, one of a handful in the United States that specializes in water-borne pathogens, also found four of the units colonized for Legionella, the bacteria associated with Legionnaire's Disease.

John Rhis, a microbiologist who is vice president of Laboratory Services at Special Pathogens Laboratory, made headlines in June when he released his findings at the national conference of the Association for Infection Control and Prevention.

“If the unit was responsible for contamination with (NTM), it makes sense that these other organisms were contaminating the sterile field as well,” Rhis

said.

“I was shocked at the level of contamination we found. About 15 percent of the samples we tested were so heavily contaminated with bacterial or fungal overgrowth that they were uninterpretable. So, the actual number of positive tests might have been higher,” he said.

Rhis said the NTM infections are so rare that many hospitals would never have tested for it.

“That's why it took so long for this to be worked out. It's an unusual pathogen, and it's pretty amazing that the link was even made,” he said.

No recalls yet

Despite Rhis' findings and safety alerts from regulatory agencies, there have been no recalls of the machines that play a critical role in regulating the temperature for patients undergoing open-heart surgery.

Hospitals that used the 3T devices have taken varied approaches to the issue. Some have placed the heater-cooler devices in adjacent rooms or behind protective coverings. Some have opted to review patient records internally rather than put out a general alert, while others such as Allegheny Health Network have replaced the units and notified patients of the potential for problems.

Dr. Sam Reynolds, chief quality officer for AHN, said officials at West Penn and Allegheny General began assessing the situation and adopted enhanced cleaning procedures for the devices immediately after the FDA advisory came out last fall.

“At the end of year we purchased new devices from a new company. But they were on back order. And until that time we had to use the heater-cooler units

we had," he said.

At the same time, AHN began identifying and notifying everyone who had open-heart surgeries from August 2012 through March 2017. The network also posted a notice and information on its website.

Reynolds said only about 50 of the 3,000 patients who were notified of the risk called to ask additional questions.

He said only "a handful" have come in for face-to-face assessments and no NTM infections have been identified yet.

Officials at Excela Health System in Westmoreland County said it was never an issue there because the hospital did not use the 3T devices.

A spokeswoman for UPMC, the region's other major center for heart surgery, confirmed that it has three of the 3T units and has been using them since 2012, but opted not to contact patients.

Two years ago, when alerts first went out, UPMC adopted the enhanced disinfection and utilization methods the CDC recommended, UPMC spokeswoman Wendy Zellner said in an email.

"We have done multiple in-depth evaluation of the patients who have been treated with these machines at UPMC and have so far found no evidence of infection," Zellner wrote.

"These machines are scheduled to be replaced in the near future. Because our patients are at extremely low risk and since notification of patients has so far not demonstrated any benefit — but does have the potential to induce significant anxiety — we have decided that patient notification is not warranted at this time," she wrote.

Debra Erdley is a Tribune-Review staff writer. Reach her at 412-320-7996, derdley@tribweb.com or via Twitter @deberdley_trib.