Open-chest devices pose infection risk to more patients, new research shows

A device used routinely in open chest surgery may have put many more patients at risk of infection from a rare but deadly form of bacteria than earlier believed, according to a study by a Pittsburgh researcher released Wednesday.

The research, released at a national conference of infection prevention experts in Portland, Ore., has prompted at least one local hospital system, Allegheny Health Network, to begin notifying about 3,000 patients who were involved in such surgeries at either Allegheny General Hospital or West Penn Hospital since 2012. UPMC said it is not notifying its patients.

The problem with the device — heater-cooler units that are used to warm or cool patient bodies — has been known since early 2015, after research in European countries first linked infections in patients to contamination in one particular type of unit, the Stockert 3T made by LivaNova of Germany.

U.S. regulators have since found the same problem they suspect led to the infections from the Stockert 3T — cooling fans aerosolizing leaking water — was possible with other manufacturers as well. Almost all of the reported cases of infection have come from the Stockert 3T, but a few have been associated with other manufacturers' units as well.

The new study by Jack Rihs, head of laboratory services at Special Pathogens Laboratory in the Pittsburgh Bluff neighborhood, found that the rate of contamination in heater-cooler units was much higher than the U.S. Food and Drug Administration believed last fall when it said up to 500,000 people might be at risk.

In samples of water from the units — all of them Stockert 3Ts, which once made up 60 percent of the market in the U.S. — Mr. Rihs found that 33 of 89

of the heater-cooler units he tested from 23 states, the District of Columbia and Canada tested positive for mycobacterium chimaera.

“I was surprised that so many were positive,” Mr. Rihs said, “because [M. chimaera] is such a rare pathogen and to find so many in these devices all over the U.S. is unusual.”

Sam Reynolds, AHN’s chief quality officer, said he was “shocked” by the results of the study, which evaluated samples sent to Mr. Rihs’ lab by clients.

“With this new research [from Mr. Rihs] we decided to notify our patients,” Dr. Reynolds said. “It really stepped up our urgency. It showed us [the risk of contamination] is affecting a lot of [heater-cooler] units, not a few.”

AHN used six Stockert 3T units between the two hospitals, and after a U.S. Food and Drug Administration advisory notice last fall, it took the FDA and the manufacturer’s advice and put all six units through more rigorous cleaning to ensure they were not contaminated. AHN also tested all six units last fall and none of them was found with contamination. But a test earlier this year found contamination in one unit.

AHN ordered six new units last fall from a different manufacturer and has stopped using the Stockert 3Ts.

Dr. Reynold said that AHN had already done a review of patient records and it has not found any of those 3,000 patients who appear to have been infected as a result of the contamination.

The problem, Dr. Reynolds and other infection experts acknowledge, is that non-tuberculous mycobacteria like M. chimaera often do not result in signs of infection for patients for months if not years. Many patients, or their doctors, may not have connected any later infection back to the earlier surgery.

“And this bacteria has very non-specific symptoms,” Dr. Reynolds noted, including such vague signs such as fatigue, fever, pain or weight loss.

But the potential for harm once infected is real. The FDA said that during its study period last year, it received 91 reports of possible contamination. Among those reports, there were at least 79 patient infections, and at least 12 of those patients died, but the FDA and other experts believe that many cases go unreported.

UPMC said in an email statement that it uses three Stockert 3T units at UPMC Shadyside hospital, and continues to use them after beginning use of protocols the FDA recommended last fall, following a study of an outbreak at a WellSpan hospital in York, Pa. Those recommendations include protocols on how to better clean the devices and position them in or near the operating rooms during surgery to minimize potential infection.

Like AHN, it also did a review of patients' cases and found no patient infections of non-tuberculous mycobacteria that could be tied to the units.

UPMC said: "Per the CDC Health Alert Network advisory, our infection prevention team considered patient notification and, as there were no device-associated infections in our patients, it wasn't warranted."

Other Pittsburgh area hospitals — including St. Clair, Excela Health hospitals, and Veterans Affairs Pittsburgh Health System hospitals — said they did not use the Stockert 3T units, had not found any infections associated with the devices they did use, and had not notified patients because of that.

LivaNova said in an email exchange that it stopped manufacturing the Stockert 3T last fall and continues to provide loaner units to hospitals that request them and provide assistance to any hospital that asks.

"LivaNova is committed to continuing to work with regulators, clinicians and all relevant parties to resolve this important industry-wide issue and ensure 3T Heater-Cooler users have continued access to this important device that enables lifesaving cardiac surgery," the company said in a statement.

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