

23 August 2016

NSW Health replaces machines and alerts cardiologists to rare infection risk

As a precaution, NSW Health has replaced a small number of machines used in cardiac surgery following international reports of a rare infection.

NSW Health has also advised clinicians to consider infections due to the *M. chimaera* bacteria in patients who have undergone open heart surgery in the last five years.

Infection of cardiac surgery patients with *Mycobacterium chimaera* associated with a particular piece of open heart surgery equipment (specifically heater-cooler units made by Sorin) was first recognised in 2012 in Switzerland. The devices, which are widely used around the world, are thought to have been contaminated during manufacture.

The TGA (Therapeutic Goods Administration) has advised of a possible patient infection linked to the contaminated units in Australia. There have been no reported patient infections to date in NSW.

These infections are rare and the risk to patients is very low. The risk of a patient contracting an *M. chimaera* infection following valve replacement is estimated to be about one in 100,000.

Internationally around 50 patients have been identified as developing this infection between three months and five years after their operation where this contaminated equipment was used.

The four NSW public hospitals which used potentially contaminated heater-cooler units are Prince of Wales, St George, Sydney Children's Hospital, Randwick, and The Children's Hospital, Westmead.

There is a very small risk that patients who underwent open heart surgery at these hospitals in the past five years could develop this unusual infection in or near their surgical wound.

There is no ongoing risk in NSW public hospitals. The contaminated units have either been verified as clear after rigorous cleaning or have been replaced with new units.

Dr Kate Clezy, an infectious disease specialist working the NSW Clinical Excellence Commission, said: "The contamination of heater-cooler devices with this mycobacteria is associated with only one brand and we've contacted all facilities using this device to ensure they were being rigorously cleaned or replaced."

“The risk of infections to an individual patient is very small, but it’s important that we’ve alerted clinicians to the risk and put systems in place to reduce the risk further.”

NSW cardiothoracic surgeon, Dr Hugh Wolfenden, said: “Cardiac surgery is essential, but like any surgery has risks. Currently the risk from these infections is far less than the risk of not doing the surgery.

“NSW Health has been proactive in putting in place steps to minimise the risk of these rare infections,” he said

Upon receiving notification that contaminated units had been identified in NSW, NSW Health formed an expert panel involving clinicians and representatives from the Clinical Excellence Commission, Chief Executives of Local Health Districts and Health Protection NSW.

In addition to replacing and undertaking deep cleaning of affected devices, a NSW Health safety notice was issued to public and private health facilities on 8 July, and updated on 4 August, to raise awareness among clinicians of the very low risk of infection.

More detailed information was provided to cardiologists, cardio-thoracic surgeons, clinical microbiologists and laboratories, and a fact sheet for open-heart surgery patients was prepared.

NSW Health and other jurisdictions are working with the Australian Commission for Safety and Quality in Health Care to develop a national infection control guideline on minimising the risk of infection relating to the use of heater-cooler units.

“Open heart surgery is for many patients a life-saving procedure,” said Dr Kerry Chant, NSW’s Chief Health Officer. “We have worked quickly in NSW to secure uncontaminated equipment so that any risk, even though very low previously, is now mitigated.”

NSW Health recommends patients who had open heart surgery at Prince of Wales, St George, Sydney Children’s Hospital, Randwick, or the Children’s Hospital, Westmead, over the past five years who have concerns about infection risks should consult their doctor.

The safety notice, information to clinicians and the patient fact sheet are available from the NSW Health website:

<http://www.health.nsw.gov.au/Infectious/alerts/Pages/M-chimaera-and-surgery-alert.aspx>