Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Safety Update

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In this issue

TGA urges reporting of contamination after reprocessing of endoscopes

With the issue of inadequate and/or difficult endoscope cleaning attracting scrutiny from regulators worldwide, the TGA is urging Australian health professionals to be alert to the issue and potential changes to some devices' Instructions for Use.

The issue has been particularly acute in the USA, where there have been many reports of duodenoscopes cross-contaminating patients with carbapenem-resistant enterobacteriaceae (CRE), a type of intestinal bacteria.

Duodenoscopes are a type of endoscope and their complex design makes them particularly challenging to clean and sterilise (reprocess) following procedures.

Transmission of CRE often results in colonisation that is asymptomatic for many months before causing clinical infection. Clinical infections due to CRE have a 40-50% mortality rate.

The hospital and community incidence of CRE is rapidly increasing across the world due to unnecessary and excessive antibiotic use and is particularly common in Greece, India, China and many South-East Asian countries.

There has been one report to the TGA this year of a duodenoscope that tested positive to intestinal bacteria despite repeated reprocessing efforts. The bacteria involved were not CRE and no patients. were affected in the incident. The TGA urges health facilities to report any similar instances of contamination following cleaning and sterilisation

Two of the major manufacturers of duodenoscopes used in Australia have undertaken recall actions to address the issue.

Olympus has undertaken an Australian recall for product correction of its TJF-Q180V model. This recall action involved updates to its Instructions for Use regarding reprocessing and modification of a part of the device. Pentax has undertaken a recall for product correction of its ED-3490TK video duodenoscope to update its Instructions for Use regarding reprocessing.

In light of the contamination issue, the Gastroenterological Society of Australia and Gastroenterological Nurses College of Australia have been working to revise their guidelines on infection control in endoscopy. These revisions are currently undergoing consultation.

MDSU has reported on this and other reprocessing issues in September 2014, November 2015 and March 2016.

A US Senate committee has also investigated duodenoscope contamination and released its report on 13 January 2016.

The report was critical of many facets of the US health system and safety regulation and made a number of recommendations for improvements.

Medical Devices Safety Update is the medical devices safety bulletin of the Therapeutic Goods Administration (TGA)

TGA Health Safety Regulation

Non-tuberculous mycobacterium infections associated with heater-cooler devices

The TGA is urging health professionals and facilities to be alert to the potential link between the use of heater-cooler devices, particularly in open cardiac surgery, and infections with non-tuberculous mycobacteria such as *Mycobacterium chimaera*.

There have been reports internationally of surgical site infections with an unusual mycobacterial species, *Mycobacterium chimaera*, in patients who have had cardiac surgery. These have involved open cardiac procedures where medical devices have been implanted, such as cardiac valves. Investigations have linked infections with contaminated heater-cooler devices used in cardiac bypass surgery.

In Australia there have been no reported infections with *Mycobacterium chimaera* suspected of being linked to contaminated heater-cooler devices.

Non-tuberculous mycobacteria (NTM) include a number of different bacterial species, many of which are widespread in nature and can be found in water (including tap water). They are not usually a major cause of infection in the community, however in rare cases may cause infections in very ill or immunocompromised individuals. The organism is slow-growing, so infections may present some months (or years) after exposure.

Heater-cooler devices are used in Australia to warm or cool a patient to optimise medical care and improve patient outcomes. In cardiothoracic surgery, heater-cooler devices are used within the operating theatre to control the temperature of blood diverted to cardio-pulmonary bypass machines. Heater-cooler devices contain water tanks that provide temperature-controlled water for the operation of the device. This water does not come in contact with the patient.

The exact route of transmission to patients is currently unknown. Studies suggest that if bacterial contamination of the water within the device occurs, there is the potential for the device to transmit bacteria through the air (aerosolise) through the device's exhaust vent and into the operating environment.

Many overseas jurisdictions have received reports of infections, but the overall number of cases is not clear. In the United States, the FDA have received a total of 40 medical device reports of NTM infections potentially associated with heater-cooler devices as at 1 April 2016. The majority of these reports were made in 2015.

Some manufacturers of heater-cooler devices used in cardiothoracic surgery have provided updates to their Instructions for Use and provided recommendations on how to reduce the risk of water contamination and testing for the presence of the organism.

TGA activities

The TGA has launched an ongoing investigation into this issue. Current actions include:

- Consultation with experts including infectious diseases physicians, cardiac surgeons and public health experts.
- The TGA is currently liaising with all manufacturers of heater-cooler devices in Australia used in cardiothoracic surgery to ensure that the risks are appropriately mitigated for all devices.
- Ongoing monitoring and investigation of any adverse events reported in relation to this issue.

Advice for health facilities and staff

In addition to standard precautions, the TGA recommends the following:

- Consult your infectious diseases unit and infection control unit on how to adhere to the cleaning and disinfection instructions provided by the manufacturer.
- Some manufacturers have updated their Instructions for Use documents and provided additional information in the form of a "recall for product correction". Please ensure that this updated information is readily available and all relevant personnel, including infectious diseases units, have been informed of these recommendations.
- If you have concerns regarding how to follow the manufacturer's instructions, contact the Australian sponsor of the device for further clarification.
- If you are unable to access the products required for effective cleaning of the device, contact the Australian sponsor of the device.
- If your facility is undertaking microbiological screening of water in heater-cooler devices and/or operating theatres, consider the following:
  - Two microbiological methods are being recommended by some manufacturers –

Update: Since this article was published the TGA has received a report of a possible patient infection with Mycobacterium chimaera following open cardiac surgery in 2015.

More information is available in this safety alert.

The TGA's advice regarding the management of devices found to test positive for non-turberculous mycobacteria has also been updated and facilities are now advised to consult their infection control unit, infectious diseases unit and clinical teams to determine the most appropriate action for your hospital.

The previous advice has been marked by ~~strikethrough~~ text.

cultures of heterotropic plate counts (HPC) and mycobacterial cultures.

- Environmental samples should be submitted to an accredited environmental laboratory and tested using validated culture-based methods.
- Mycobacterial cultures of environmental samples requires specialised expertise, which may not be available in all facilities.
- Hospital protocols should account for the potential delay in receiving results from mycobacterial cultures, which may take 6-8 weeks.

- Some health facilities have implemented procedures to direct the heater-cooler's vent exhaust away from the surgical field to mitigate the risk of aerosolising heater-cooler tank water over the sterile field and exposing patients. This may not be possible in all facilities. If measures are taken, the TGA recommends contacting the Australian sponsor of the device and discussing the proposed method to ensure it will not affect the functioning of the device.
- Immediately remove from service any heater-cooler devices that show discolouration or cloudiness in the fluid lines/circuits, which may indicate bacterial growth. Consult your hospital infection control unit and infectious diseases unit for appropriate follow-up measures.
- Hospitals are encouraged to develop internal policies and procedures to address this potential issue. This should include access to back-up or loan devices should a device in operation become contaminated. Contact the Australian sponsor of the device in your facility to determine if a loan arrangement is possible.
- Health facilities should follow their internal procedures for assessing patients and notifying cases.

Positive results from device testing

If a device tests positive for NTM:

- ~~Do not use the device.~~ Consult your infection control unit, infectious diseases unit and clinical teams to determine the most appropriate action for your hospital.
- Implement the appropriate protocol for decontamination of the device.
- In some circumstances, a loan device may be available through the Australian sponsor.
- Report the positive result according to the protocols of your health facility.
- Report the positive result to the TGA and the Australian sponsor of the device.

Positive results from patient testing

If a patient tests positive for NTM following exposure to a heater-cooler device (such as following open cardiac surgery), consider the following steps:

- Contact the infectious diseases unit within your facility for advice on appropriate patient management and follow-up.
- If the patient has had exposure to a heater-cooler device, do not use the device and implement the appropriate testing protocol.
- Report the positive result according to hospital protocols.
- Report the positive result to the TGA and the Australian sponsor of the device.

Patient 'look backs' following exposure

Currently, there are no evidence-based guidelines available on the follow-up of patients who have been exposed to a contaminated device.

Implementing a 'look back' may be complex due to the slow-growing nature of the organism. Screening asymptomatic patients for NTM is currently not indicated. At this stage, the TGA recommends liaising with the medical director of the health facility and state/territory public health units to determine the most appropriate protocol in your jurisdiction.

Recommendations for doctors

In patients who have undergone open cardiac surgery, especially those who have had valve replacement surgery, please consider:

- As only a small number of cases have been identified globally to date, the risk to individual patients of NTM infections is thought to be very low.
- Infection with NTM should be considered in patients with surgical site infection who have had cardiac surgery, particularly if conventional cultures are negative, if infections are not responding as expected, and those with unusual presentations.
- The diagnosis of NTM infections may require specialised microbiological techniques; consultation with an infectious diseases physician or clinical microbiologist is recommended.
- Consult with an infectious diseases physician as to the appropriate management of patients with confirmed infections with NTM.
- Report any confirmed or suspected infections to the TGA and the device sponsor.

REFERENCES

Free CPD modules

Adverse event reports underpin an essential part of the TGA's safety monitoring activities as they assist with early detection of potential safety problems.

Health professionals are among those best placed to provide high quality adverse event reports, given their expertise and direct contact with patients. The TGA and NPS Medicinewise have worked together to create interactive online learning modules designed to improve adverse event reporting by health professionals.

The medical devices online learning module, along with its companion module focusing on medicines and vaccines, help health professionals build on their existing expertise and encourage them to use their skills to assist the TGA in its ongoing safety monitoring activities.

Recent safety alerts

Below are TGA safety alerts relating to medical devices published since the last edition of *Medical Devices Safety Update*.

Epipen 300 Microgram Adrenaline Injection Syringe Auto Injectors: Reports of expired EpiPen devices supplied in cartons within expiry

Mums The One one step hCG urine pregnancy test: Recall - potential decreased sensitivity

Dexcom continuous glucose monitor receivers: Recall for product correction - potential for audible alarms not sounding

Medtronic Reveal LINQ insertable cardiac monitor: Hazard alert - potential for premature replacement alert

LCS Complete RPS Knee System (used in knee replacements): Hazard alert - higher than expected revision rate

ConceivePlease one step hCG urine pregnancy test: Recall - potential decreased sensitivity

What to report? Please report adverse events, as well as near misses

The TGA encourages the reporting of any suspected adverse event or potential adverse event relating to a medical device. Adverse events can involve actual harm to a patient or caregiver, or a near miss that may have resulted in harm.

Some issues relating to medical devices that may lead to adverse events and prompt you to report include:

- mechanical or material failure
- design issues
- labelling, packaging or manufacturing deficiencies
- software deficiencies
- device interactions
- user/systemic errors

Suspected adverse events or near misses can be reported directly to the TGA:

- **online** at www.tga.gov.au (click 'Report a problem')
- **by emailing** iris@tga.gov.au
- **by mail** to IRIS, TGA, PO Box 100, Woden ACT 2606
- **by fax** to 02 6203 1713

For more information about reporting, visit www.tga.gov.au or contact the TGA's Medical Devices Branch on 1800 809 361.

For the latest information from the TGA, subscribe to the TGA Safety information email list via the TGA website

For correspondence or further information about Medical Devices Safety Update, contact the TGA's Medical Devices Branch at iris@tga.gov.au or 1800 809 361

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