Australian Government
Department of Health
Therapeutic Goods Administration

Medical Devices Safety Update

Volume 6, Number 1, January 2018

In this issue

Inappropriate use of scalpel blade removers potentially transmits infection

A recent device incident report submitted to the TGA highlights the issue of inappropriate use of scalpel blade removers during surgical procedures potentially transmitting infection between patients.

Scalpel blade removes are designed to enable one-handed removal of the blade from a scalpel handle. The scalpel blade and handle are partially inserted into the unit and the scalpel blade is automatically removed when the handle is withdrawn from the remover. The scalpel blade is retained within the unit.

These units are used by health professionals to help prevent injury from handling contaminated scalpel blades and are commonly located in or near operating theatres or clinics where scalpels are used for surgical procedures.

They are usually mounted to the wall inside the theatre or just outside the theatre where the trollies are tidied up after surgical procedures.

They are not classed as medical devices and are simply aids for safe blade removal and receptacles for used/contaminated blades.

Risk of transmitting infection

When a used scalpel blade and handle are inserted into the unit, the handle potentially becomes contaminated with microorganisms and blood-borne viruses.

The handle should not be used again until it is reprocessed and sterilised.

The incident report submitted to the TGA stated that some users of a scalpel blade remover in an operating theatre were using it to remove scalpel blades and then re-fitting new blades to the same handles before continuing with procedures.

The facility involved in the report has removed the scalpel blade remover from the area where the practice was identified.

According to staff interviewed at the time, the practice of using the units in this way was taught at university.

Advice for health professionals and facilities

Health professionals and facilities are advised:

- To ensure staff are aware that these receptacles are not sterile and should not be used to remove blades from scalpel handles during operations or procedures.
- Handles that have been inserted in the unit are potentially contaminated and should not be returned to the sterile field as there is a high risk of cross-infection.
- If facilities have concerns with the use of these receptacles they should prevent them from being accessed during surgical procedures.

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

TGA Health Safety Regulation

ECRI lists ransomware as 2018 top hazard

Ransomware and other cybersecurity threats have been named as the top health technology hazard worldwide, followed by endoscope reprocessing failures and contamination of mattresses and bedding.

The ECRI Institute (formerly known as the Emergency Care Research Institute) publishes a list each year detailing what it believes to be the top 10 health technology hazards for the coming year.1

ECRI Institute has listed 'missed alarms' as the fourth most pressing hazard in 2018. Clinical alarm hazards had topped the ECRI Institute list in 2012, 2013, 2014 and 2015. They were listed second in 2016 and third in 2017.

The full list

The ECRI Institute's top 10 hazards list for 2018 is:

1. Ransomware and other cybersecurity threats to healthcare delivery can endanger patients. (This issue was covered in MDSU in March 2016.)
2. Endoscope reprocessing failures continue to expose patients to infection risk. (This issue was covered in MDSU in September 2014, March 2016 and May 2016.)
3. Mattresses and covers may be infected by body fluids and microbiological contaminants.
4. Missed alarms may result from inappropriately configured secondary notification devices and systems. (This issue was covered in MDSU in January 2014, May 2014 and January 2015.)
5. Improper cleaning may cause device malfunctions, equipment failures, and potential for patient injury. (Aspects of this issue were covered by MDSU in November 2015 and May 2017.)
6. Unholstered electrosurgical active electrodes can lead to patient burns. (Related issues were covered in MDSI in September 2015.)
7. Inadequate use of digital imaging tools may lead to unnecessary radiation exposure.
8. Workarounds can negate the safety advantages of bar-coded medication administration systems.
9. Flaws in medical device networking can lead to delayed or inappropriate care.
10. Slow adoption of safer enteral feeding connectors leaves patients at risk.

The purpose of the list

ECRI Institute said the list did not enumerate the most frequently reported problems or the ones associated with the most severe consequences, although such information fed into the analysis. Rather, the list reflected its experts' judgment about which risks should receive priority now.

The create the list, ECRI Institute engineers, scientists, clinicians, and other patient safety analysts nominated topics for consideration based on their own expertise and insight gained through:

- investigating incidents
- testing medical devices
- observing operations and assessing hospital practices
- reviewing literature
- analysing health technology problem reports
- speaking with:
  - clinicians
  - clinical engineers
  - technology managers
  - purchasing staff
  - health systems administrators
  - device suppliers.

All the items on the list represented problems that could be avoided or risks that could be minimised through the careful management of technologies.

Focus on solutions

The TGA advises health professionals to consider ways to mitigate risks within the clinical settings in which they work. Health facilities should:

- set up effective risk management programs that involve clinicians, biomedical engineers, hospital management and administrative staff.
- ensure that responsibilities are clearly assigned to the relevant personnel.
- ensure all staff carefully read and fully understand the Instructions for Use for devices they use and are responsible for.

REFERENCE

1. Top 10 Health technology Hazards for 2018, Health Devices, November 2017. Emergency Care Research Institute (registration required).

Registry adds surgeon and hospital variation to joint replacement report

For the first time, the Australian Orthopaedic Association National Joint Replacement Registry has addressed the issue of individual surgeon and hospital variation in outcomes and examined the role that prosthesis choice has in that variation.

An additional 113,933 hip, knee and shoulder joint replacement procedures conducted in 2016 have been included in the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) 2017 annual reports. These reports, which were published on 1 October 2017, offer insight into the performance of orthopaedic implants being used in this country, providing the TGA with vital data to underpin its monitoring of orthopaedic implant safety.

A total of 130 implants with higher-than-expected revision rates were identified in the reports, consisting of 76 hip, 46 knee, seven shoulder and 1 ankle prosthesis combination. A total of five (four hip and one knee prosthesis combination) were newly identified in 2017. The TGA is currently investigating why these newly identified implants may be having a high rate of revision.

Except for the five new implant combinations, all of the other 'identified' implants have been previously investigated by the TGA, and in coming months we will re-review all implants that are 'identified and continue to be used' to ensure that our actions in relation to those implants remain appropriate.

All surgeons who have used particular implants are notified when the TGA undertakes regulatory action involving those implants, giving them the information they need to optimise patient care. The registry undertook activities in 2017 to improve this information by providing more detailed data to enable surgeons to more comprehensively assess their individual performance.

Among many other functions, the AOANJRR provides population-based data on the comparative outcome of individual prostheses used in Australia. The annual reports contain information about orthopaedic implants that are having higher-than-expected rates of revision. The main AOANJRR report is based on an analysis of 1,237,576 primary and revision joint replacement procedures (545,831 hips, 653,480 knees and 38,265 shoulders) performed before 31 December 2016. Shoulder procedures were incorporated into the main annual report for the first time in the 2016 annual report (shoulders had previously been discussed in one of the AOANJRR's many supplementary reports) and appear for the second year running in the main report.

The reports compare the performance of individual implants with all implants of that type and identify those that do not appear to be performing as well as the others, using the revision rate as a measure. Joint replacement surgery is considered to be one of the most effective forms of surgical intervention and the overall revision rates are generally low, even for many of the implants for which the revision rate is considered to be higher-than-expected.

Expert advice

In reviewing whether the implants identified in the reports require regulatory intervention, the TGA seeks advice from orthopaedic experts on the Advisory Committee on Medical Devices (ACMD). The committee advises the TGA whether the reported revisions are of significant clinical concern. Based on this advice and other information, including that provided by the relevant sponsor, the TGA will then take regulatory action if required.

When regulatory intervention is necessary it is reported to all surgeons who have used the implants through a hazard alert and details of the action/intervention are published on the TGA website.

Elevated revision rates

Higher rates of revision are of concern because, as with any major surgery, orthopaedic surgery is associated with significant health risks. However, there are many reasons why a particular implant may be having a higher-than-expected rate of revision (including patient-related factors such as age and level of activity) and an elevated revision rate does not necessarily mean that the TGA needs to take regulatory action.

The AOANJRR annual reports list a total of 40 implants identified before 2017 that had higher-than-anticipated revision rates and were still being used during the reporting period. The TGA may choose to continue monitoring implants and not take regulatory action, even though the revision rate is higher-than-anticipated, for reasons including:

- the implant had been used in a select patient population that is at a higher risk of revision
- use of the implant offers unique benefits that compensate for the higher risk of revision
- the implant is very new to the market, has been used in low numbers and other information indicates the revision rate will decrease rapidly.

Identified and no longer used

There are 85 implant combinations in this category. In many cases (48) they were identified after the implant combination had been withdrawn from the market or was no longer used. In the other cases (37) the implants were withdrawn after TGA interventioninvestigated the higher than expected rate of revision.

Recent safety alerts

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

TGA actions after review into urogynaecological surgical mesh implants: TGA undertakes regulatory actions after review into urogynaecological surgical mesh implants

Philips IntelliVue MX40 wearable patient monitor: Update following revocation of suspension

Infections associated with heater-cooler devices: Update to statement regarding heater-cooler devices following recall action and suspension of LivaNova 3T heater-coolers

Infant/Child reduced energy defibrillation electrodes: Safety advisory – risk of serious injury or death due to incorrect instruction artwork

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

Medical Devices Safety Update is written by staff from the Medical Devices Branch

Editor:
Ms Pamela Carter

Deputy Editor:
Mr Aaron Hall

TGA Chief Medical Adviser:
Adjunct Professor Tim Greenaway

Contributors include:
Dr Jorge Garcia
Mr Shawn Hazel