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SafMed Steri-View

A SPECIALIST NEWSLETTER IN STERILIZATION & INFECTION PREVENTION TOPICS FOR HEALTHCARE PROFESSIONALS

Sterilization Breach: Whose Fault Was It, Theatre Or CSSD?

An incident occurred in a hospital in Australia in 2004 that was a shocking reminder of how easily things can go wrong in the CSSD and the Operating Theatres. But who was to blame for this incident?

The Incident

The staff in the operating theatres at Southern Health in Australia discovered an item packed in a SteriReel (paper plastic pouch) where the external and internal chemical indicators had not changed colour. It appeared the item had been cleaned and packed but not sterilized. The hospital used a manual track and trace system so the item had a batch label. Having noticed this breach a recall of all items with the same batch number was initiated.

Example of manual batch label

Two registered nurses were allocated to check all sterile storage areas in the operating theatres, wards, emergency rooms and the CSSD to look for items with the same batch label. On this first recall inspection, another two unsterile items were found. It was difficult to check all areas thoroughly so the inspection process was repeated. During the second inspection another two unsterile items were found, bringing the total to five.

It was noted on the autoclave records for this batch number that six items had been placed in that load, meaning that one item was left unaccounted for, and may have been used on a patient. The number of items in the load could have been recorded on the autoclave envelope for example (as depicted).

The policy in the hospital was to affix the batch label to the patients' peri-operative documentation. As a result two staff from the operating theatres were allocated to review 973 patient peri-operative records. They were looking for the specific batch label, expecting to find the one item that was unaccounted for. To their surprise they found the same batch label on the records of seven patients. This meant that the autoclave records were incorrect as 12 items where theoretically processed in this batch, not six. In addition it meant that seven patients may have been treated with unsterile items. The seven implicated patients were contacted and offered testing for bloodborne pathogens and counselling.

Track-and-Trace Systems

Many hospitals in a number of countries have implemented medical device track and trace systems. In fact in many countries like Japan, Ireland and the UK implementation is mandatory.

SafMed Documentation Envelope: Manual Track-and-Trace System

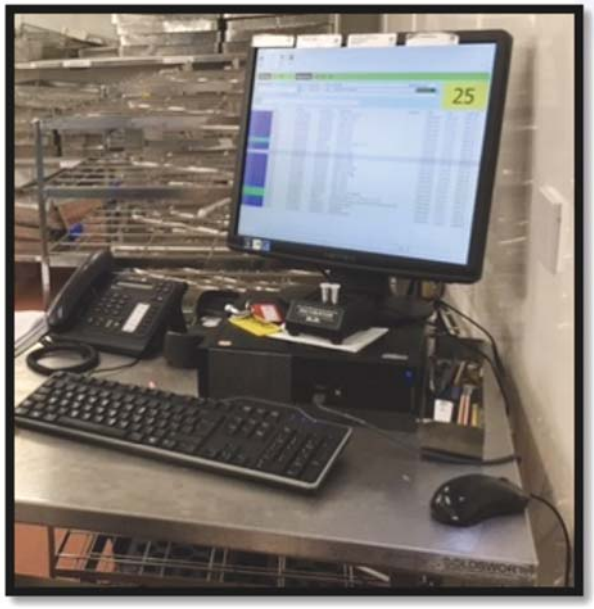
Track-and-trace systems should identify and record the cleaning and sterilization methods used on medical devices, the identity of each person undertaking decontamination of these devices at each stage of the cycle and they should identify the patients on whom they have been used (HTM, 2016).

The manual track-and-trace system thankfully made it possible to perform a batch recall. The recall was time consuming and not necessarily accurate as there was no way of knowing where the items were dispatched to. In addition, only by tediously reviewing 973 patients' records could the actual patients that the unsterile items were used on, be identified. The manual system used by the hospital at the time of incident wouldn't be compliant with the Health Technical Memorandum

(HTM) 01-01: 2016. The manual system was not able to identify and record the decontamination at each stage of the cycle and who performed these tasks.

The use of an electronic track-and-trace system would facilitate the capturing of data at each point of the decontamination cycle allowing the hospital to easily track, trace and record each step of the decontamination process. Because so much data is recorded throughout the process an electronic track-and-trace system would help a hospital to better manage their assets, to measure and improve staff productivity, identify staff training needs, improve their compliance and ensure patient safety! The data recording is facilitated by marking each set with a unique barcode, by having workstations and scanners at each point of decontamination, and by having individual staff logins.

The FingerPrint Tracker System for example records data at each of these points



Workstation

At the end of the decontamination process, each set has a printed label. By scanning the barcode all details regarding the decontamination process are easily accessed.

Example of a barcode

Dispatch

While investigating the breach of sterilization it was noted that operating theatre staff routinely entered CSSD to take items. It is possible that during this incident the items were removed from CSSD before they were actually sterilized. If this was the case, and if an electronic system was in place, they would have needed to scan the items out of the CSSD. When doing that the system would have issued an alarm, alerting them to the fact that the items had not been through an autoclave yet.

In Conclusion

Whose fault was it, you may well ask? This breach of sterilization was a systems issue and could have been avoided if a suitable electronic track-and-trace system was in place. Thankfully the hospital had a manual system in place which, at least, is better than nothing. Patient safety and adherence to Standard Operating Procedures is just one of the many advantages of an electronic track-and-trace system.

References:

Cooper, E. Breckon, K. *Sterilization breach.* Journal of Hospital Infection 2005; 379

Health Technical Memorandum (HTM) 01-01 United Kingdom: *Management and Decontamination of Surgical Instruments (medical devices) Used in Acute Care. Part A.* 2016. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/536144/HTM0101PartA.pdf

McMahon, A. *The potential benefits of a traceability solution for surgical trays in the Irish Health Service.* Dublin. University of Dublin, 2012. Accessed 25 August 2016. https://www.cs.tcd.ie/postgraduate/health-informatics/assets/pdfs/Alana McMahon_MSc Health Informatics 2012.pdf

Feedback From The CFSA Congress 2016

The CFSA (CSSD Forums of SA) hosted a congress at Africa Health in 2016. The event was well attended and the room was filled to capacity. Here is a summary of some of the presentations (based on the abstracts supplied by the presenters) given over the two days:

IT'S ALL ABOUT QUALITY - YOURS, MINE AND THEIRS
Sue Armstrong: **University of Witwatersrand (PhD Nursing)**
Dr Armstrong explained that the emphasis in South Africa is currently on meeting the requirements of the National Core Standards set by the Office of Health Standards Compliance. In order to make it possible to reach these standards, all healthcare workers should be involved and be motivated to be part of these important goals. To make the National Core Standards a reality there needs to be total buy-in.

MAINTAINING FACILITIES TO ENSURE QUALITY - TRAINING IS KEY
Coralie van Reenen: **CSIR (BArch, MSc in Applied Science) Research Architect**
According to Coralie, the best healthcare facilities are only as good as the maintenance programme overseeing them. It's important that the team designing a healthcare facility convey information to those who will take care of the facility for its lifespan. Design should not stop at the completion of construction. The entire life-cycle of a facility, from conception to decommissioning, should be designed and monitored. It has been observed that maintenance staff, while well-trained in their particular discipline, are not always adequately trained and prepared for working in the unique environment of healthcare facilities.

REPROCESSING OF 'SINGLE-USE' ORTHOPAEDIC IMPLANTS: A STUDY ON THE EFFECTS OF REPEATED REPROCESSING ON SINGLE-USE SCREWS IN SCREW CADDIES
Terry McAuley: **Sterilization and Infection Prevention Consultant, Australia**
Terry presented her research performed on reprocessed orthopaedic screw caddies. 10 new screws (controls) and 10 screws from three patient-ready screw caddies were observed under high magnification. They were observed for contamination, corrosion, deterioration and damage. This study demonstrated that exposure to multiple reprocessing cycles causes contamination, corrosion and deterioration of single-use screws in screw caddies. As a consequence, the author recommends that the use of screw caddies should cease and individually packaged and sterilised, single-use plates and screws should rather be used.

HOW ARE GASTROSCOPES AND COLONOSCOPES CLEANED IN THEATRE?
Eileen Fisher: **President of SAGINS (The South African Gastro-intestinal Nurses Society)**
Flexible endoscopy is a common clinical procedure used to diagnose and treat many conditions. The use of endoscopy continues to grow and many specialized procedures are now being performed. It is of absolute importance that all patients undergoing endoscopy be protected from infections. It is essential that endoscopes are reprocessed thoroughly and that set guidelines are strictly adhered to. There are a number of reprocessing (cleaning and disinfection) steps that must be performed, no matter what circumstances you work under.

TRIALS AND TRIBULATIONS IN LOAN SETS

Marietjie du Toit: **National Infection Prevention Specialist PGD Nur Ed**

SANS 1541:2014 (Hospital loan sets) was published in 2014. There are still many difficulties (trials) associated with loans sets. The delivery time is still a major problem; the 'certificate of sterility' cannot necessarily be accepted as a true reflection of decontamination. Thankfully the loan set standard has created awareness around loan sets not seen before. CSSD, Infection Prevention and Theatre staff must work closely to ensure that all instruments used on patients are sterile in order to improve patient outcomes, and they must ensure that no harm is done to any staff member when handling a too heavy set.

THE ROLE OF LEADERSHIP IN CREATING A QUALITY AND SAFE WORKING ENVIRONMENT

Tsakane Joyce Selesho: **Clinical Tutor and Infection Control Facilitator**

Joyce presented a talk about the importance of self-leadership and the role of leadership in a quality management system. Leadership is an important pre-condition to ensure the continuity of a quality system in an organisation.

CFSA Congress 2017

This year there will be two CFSA congresses. In March 2017, CFSA will team up with the South African Federation of Hospital Engineering (SAFHE) and the Clinical Engineering Association of South Africa (CEASA) at their congress in Durban. In June 2017 there will a congress at the Africa Health trade show. For more information please contact Denise Sheard at **denise@gfc.co.za or visit www.facebook.com/cssdforum**

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Courses in Decontamination and Sterilization

These courses are run at various venues throughout South Africa and sponsored by SafMed. The courses are not product related and are run by Qualified Nursing lecturers who are experts in the field of Theatre and CSSD.

The two courses are known as: ***Foundation Course in Sterilization and Decontamination (One day)***
The Advanced Course in Decontamination and Quality Management (One day)
In order to attend these courses an application form must be submitted.

For course dates and application forms please contact:

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