External Review of Recent Event at Hawkes Bay District Health Board

Reviewers

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OVERVIEW

Purpose of a Sterile Service Unit

The purpose of a Sterile Service Unit (SSU) is to provide the reprocessing of surgical equipment and to ensure that these items are free from bacteria and pathogens to prevent Surgical Site Infection (SSI) occurring through cross-infection. The effect of incorrect reprocessing of equipment has the potential to cause SSIs in patients which prolongs hospital stay, increases cost to the organisation and has a direct effect on the patient.

"SSIs can cause emotional and financial stress, serious illness, longer hospital stays, long-term disabilities, and can result in loss of life."

(Health Quality Safety Commission (HQSC), 2019)

The consequences for patients, as well as health services, means that the prevention of SSIs is extremely important, therefore following strict reprocessing and sterilising standards are essential in order to minimize risk to both patients and the organisation.

Australia and New Zealand have adopted a recognised registered set of standards by which organisations can mitigate and reduce risk to patients by following set procedures using a systematic approach. These are Australian and New Zealand standard AS/NZS4187:2014 and normative references contained therein. Contained within the standards are details of each process with an end process of tracking items sterilised to enable recall of items which have been through the process or patients as a result of post-identification of possible autoclave faults.

The SSU is a complex area where the main purpose of the unit is to process equipment through a systemic process of decontamination, appropriate packaging, sterilisation, and contain a tracking label, then stored in an appropriately designed area where staff are able to locate and retrieve as necessary. A SSU is also required to have appropriately educated / trained personnel who have completed a course of study in sterilisation techniques and processes, and shall include resources such as policies, procedures and guidelines which are easily accessed and also maintain records of prior sterilisation processes for follow-up and audit.

BACKGROUND TO EXTERNAL REVIEW

Following the events that occurred at Hawkes Bay District Health Board (HBDHB) between the periods of 1 - 11 February 2019 an internal review was undertaken by HBDHB. The purpose of the review was to demonstrate HBDHB's ongoing commitment to improve and protect the health and safety of the patients and public.

The review covered all aspects of the sterilisation failure and subsequent use of unsterile instruments on patients, risk mitigation and recall of potentially affected patients. The review was extremely thorough and is attached. The internal review documents were sent to the external reviewers on the 12 March 2019 for consideration prior to a site visit.

The Ministry of Health and HBDHB senior management team agreed that an external review of their findings was warranted in order to assure the general population of Hawkes Bay that they were not at any major risk going forward from the event and that all practical steps have been taken to prevent a recurrence in the future.

QUESTIONS FOR EXTERNAL REVIEWERS FROM HBDHB

Prior to the external review HBDHB issued a set of questions for the reviewers:

- Are the external reviewers satisfied with the three root causes identified?
- The internal review teams Terms of Reference restrict the investigation from individual staff blame. Are the external reviewers satisfied that this area was not defined within the report?
- Do the external reviewers consider that the tracking slips and scans used in the Dental clinic should be recommended for use in all departments for invasive procedures?

The identified roots causes were:

1 Full confirmation of sterilisation was not confirmed before instruments were removed from Autoclave 3.
2 Staff failed to follow HBDHB sterilisation policy and protocol checks prior to equipment dispatch from the Sterile Services Department.
3 There was a system wide failure to follow HBDHB sterilisation policy and protocol checks of sterilisation code strips on pouches and packs prior to their use in clinical department.

PROCESS UNDERTAKEN BY EXTERNAL REVIEWERS

External reviewers were invited to HBDHB to meet with the HBDHB internal review steering group personnel involved in the management of the event. The externals reviewers met with those involved to discuss the report and findings and to ask further relevant questions.

The external reviewers then took the opportunity to visit SSU as well as the Villas, District Nursing and Dental Environments. The aim of the visit to the various areas was to put the event into context as well as talk with staff who work first hand in those areas, enabling the external reviewers to answer the questions above and to offer recommendations to HBDHB to implement as well as recommendations that can be put into place as soon as possible on a national scale and supported by the Ministry of Health to prevent this occurring elsewhere.

FINDINGS FROM EXTERNAL REVIEW

FINDING ONE

The external review highlighted that on the evening of 1 February 2019 when the load was put into the autoclave there were three main factors that contributed to the event occurring. These were:

1) The technician did not recall hearing the steriliser begin its cycle after pressing the start button.

2) The printer on the autoclave had not been working for some months and this would have signalled the commencement of the cycle and would have identified at the conclusion of the cycle as to whether all sterilising parameters had been met. The review team were concerned that other loads may have potentially been unsterile due to this printer being out of action for a lengthy period of time. However further detailed discussion with members of the SSU staff and the HBDHB Internal review team allayed this concern. HBDHB were able to fully demonstrate that no other steriliser load had failed to sterilise and there was not an increased risk to the patients or the public.

3) The SSU technicians finished their shift for the night and passed responsibility for the unloading of the autoclaves to nursing staff who are not trained in sterilising technology.

Recommendations:

1) After loading the autoclave the technician does not leave the area until such time as there is evidence that the cycle has commenced. As per HBDHB CSSD policy, the technician shall identify on the autoclave printout where the cycle commences and at the end of the cycle, the technician shall sign that the load has passed and sign off on the printout.

Recommendation

It is recommended that there is regular auditing of this process.

2) It is noted that the printer on the autoclave has now been replaced and the start button inspected for function. In accordance with AS/NZS4187:2014 S8.7.1:

"Sterilising equipment shall be checked to ensure that it is functioning as intended each day, prior to being used for sterilisation of reusable medical devices. The process record shall be checked at the completion of each sterilisation cycle to verify that the process was delivered in accordance with the validated specification."

With a non-functioning printer on the autoclave for some time, the standard was not being followed. Additionally section 9.1 of the standard states:

"Prior to the release of an RMD from each process e.g. sterilisation, the process record cycle shall be checked to ensure the process has been delivered in accordance with its specifications."

Recommendation

It is recommended that all washer decontaminator and sterilising equipment is repaired immediately when a fault is detected, in order to ensure that the end product is delivered by a validated process and meets the requirements of the standard.

3) It is noted that the last load was placed into the autoclave at 22:45 PM and then the sterilising technician completed their duty at 23:00 PM after handing over responsibility for the autoclave load to the nurses on duty in theatre. It is the role of the sterilising technician to be accountable for all loads that are undergoing sterilisation. The scope of practice for sterile technicians outlines in section 8.3 and 8.4 the competencies required for operating the sterilisers and for the completion of the sterilisation procedure. This includes safe handling, traceability, monitoring, documentation and recording. The scope of practice for registered nurses does not include sterilising technology but is rather based on nursing skills.

Recommendation

It is recommended that no load be placed into the autoclaves any later than one hour prior to the conclusion of the rostered evening shift in the SSU e.g.10:00pm for an 11pm shift finishing time. This will allow for processing and release of the load to cooling prior to the sterilising technician completing their allocated shift. Recommended practice and sterilisation standards state no loads are to be left in the steriliser overnight.

It is further recommended that nursing staff do not undertake the duties of the sterilising technician as it is not within their scope of practice.

FINDING TWO

There was no clearly marked areas where items were waiting to be loaded into the autoclaves as opposed to items which had been removed from the autoclaves and awaiting release for use. AS/NZS4187:2014 S6.5.2d states that:

"Unloading the steriliser-The area in which sterilised items are unloaded shall be controlled. The environmental conditions in this area shall not adversely affect the quality of the processed RMD. RMD's sterilised by moist heat or dry heat process shall be allowed to cool prior to handling."

Recommendation

It is recommended that clearly marked out zones are identified for storage of unsterile items prior to sterilisation and sterile items that are cooling. Additionally only those staff employed as sterile technicians shall enter this area and remove sterile items to the place of storage in the sterile store.
Note: The HBDHB SSU have already drawn up plans to modify this area and it would be encouraged that HVDHB re review these in light of these findings.

FINDING THREE

The issue of fast tracking instruments sets throughout the day was cited as a reason why loads were placed in the autoclave at a late hour. SSU staff felt there was a requirement to rush everything through in case the equipment was required overnight. While SSU received a copy of the next day's elective lists they were unsure what was required as a priority.

Recommendation

It is recommended that it is communicated clearly from theatre as to which sets are a priority for the following morning lists. This could be on a whiteboard whereby theatre staff document what is required.

Repeated fast tracking of instrument sets is not best practice nor best utilisation of SSU time. It highlights that there may be a potential deficit of essential instrument sets.

Recommendation

It is recommended that there is an urgent review of the trays that are being consistently fast tracked on a daily basis and that there is consideration for an increase in the number of these sets.

FINDING FOUR

As identified in Finding One, the printer on the autoclave had not been operational and the start button on the autoclave was dysfunctional. It is noted that this has now been corrected. The external review team noted that there was no preventative maintenance contract in situ for the quarterly maintenance and annual validation processes for the autoclaves and washer disinfectors. Rather this is undertaken on an irregular basis. Had there been a contract in operation then the contractor would have this scheduled at regular intervals and the printer incident would not or should not have occurred.

Recommendation

It is recommended that there are maintenance contracts for regular scheduled maintenance of sterile services equipment as directed by the standard AS/NZS4187:2014

FINDING FIVE

HBDHB operate the MAQS tracking system to identify and report on all aspects process of reprocessing a reusable medical device (RMD). It is understood that this system is to be upgraded in early April 2019.

The standard AS/NZS 4187:2014:2.4.3.2 (b) states that traceability / tracking system shows:

(i) Sterilising process cycle number and date of sterilisation.

(ii) Identification of the steriliser, e.g. steriliser identification number or code.

(iii) Identification of the person responsible for sterilising the RMD and the date of sterilisation.

(iv) Identification of the person responsible for release of the RMD (sterilisation load) documented evidence of attainment of process parameters e.g. process/record printout. This can be electronic or manual. Where an electronic system is in place, procedures should be in place to verify attainment of process parameters at the conclusion of every cycle.

HBDHB protocols clearly define the actions to be undertaken by the sterile technicians when loading and unloading the autoclaves. On the day of the event the steriliser concerned was not identified by number or bar code for tracking. There was not documented evidence available that the process parameters had been met. The sterile technician is responsible for the loading and unloading of the autoclave however deferred the responsibility for unloading to a third party.

Recommendation

It is recommended that the tracking system upgrade includes lock outs on each step of the process of tracking, e.g. unloading cannot occur until there is evidence of sterilisation.

Instrument sets which are processed by SSU are tracked through to the patient in theatre and this meets the requirements of best practice. This event highlighted that not all RMD were able to be traced back to the patient particularly in wards and clinics which were out of the perioperative environment. The dental services at HBDHB were doing an excellent job of trying to manage tracking their sterile instruments to patients. However the manual tracking of RMD to patients and all the relevant documentation required is time consuming and could be more effectively managed if tracking were available to all users of RMD.

Recommendation

HBDHB gives consideration to expanding the scope of the tracking system to include tracking of RMD to all wards and clinics who utilise sterilised RMD. This will require access to a PC and scanner loaded with access to the tracking system similar to the programme used in theatre. The long term benefits of risk mitigation and patient safety and staff education will far outweigh the capital cost of installing the system to these areas.

FINDING SIX

In order to adhere to and excel in best practice in sterilising technology it is vital that all sterile technicians who are employed by HBDHB achieve the minimum qualification of old Level 3 or current Level 4 Certificate of Sterilising Technology. It is noted that not all sterile technicians hold this qualification. Furthermore, as a professional group under the umbrella of the Allied Health

Directorate, sterile technicians should be encouraged to have completed professional portfolios for registration with their professional body. This practice encourages continuing professional development of the sterile technician.

It is noted that there is currently no educator specifically dedicated to the training and education of sterile technicians. Professional development is by the technicians own volition, by visiting company representatives and when the sterile services manager has time. Sterile Services is a recognised profession in its own right and therefore requires specific speciality knowledge and skills.

Although the dental services had good knowledge and processed in place the other villas were unable to identify if items had been sterilised as they were unaware of the changes to the indicators on the packs, rather they took it on trust that if the item was supplied by CSSD then it 'must be sterile.' On further investigation external customers could not show they understood the importance of checking integrity of sterile items prior to opening and the correct storage of the RMD's. This has been partially addressed since the events on 1st February by ensuring all departments have visual aids to show changes in indicators on packages.

The standard AS/NZS 4187:2014:9.5 states that *"a reprocessed critical / semi-critical RMD shall be handled, transported and stored in a manner which minimizes the risk of contamination"*. Maintaining sterility of RMDs and items purchased sterile by the HSO is dependent on maintaining a suitable storage environment, education of staff and the implementation of transport systems which protect package integrity until the point of use.

Recommendation

HBDHB appoints to an educator role specifically focused on Sterile Technicians training and professional development. This role could include allocated hours dedicated to the education of external customers who use the SSD service. This was include education and auditing as per the recommended standards and audit tool AS/NZS4187:2014. The educator role would be best suited would be best suited to a senior sterile technician who has completed the advanced certificate in sterile technology or the diploma in sterile technology or working towards this. It is envisaged that the role would require a minimum 0.5to 1.0FTE.

SUMMARY

On the day of the reportable event and potentially on other days leading up to the event:

- Sterilisation processes did not conform to the standard AS/NZS4187:2014.
- There was no traceability or sterilisation records for follow up or audit process.
- Loads were not correctly checked or verified as having completed the full sterilisation cycle ensuring correct pressure and heat had been reached and maintained for the correct period of time.
- Sterilisation identifiers were not visible therefore staff not able to verify sterility.
- Flow for reprocessing of equipment from dirty to clean in SSU needs amending. Unit does not meet the current requirements for a SSU and is not conducive to best practice and the direct health and wellbeing of those personnel initiating the processes.
- There needs to be maintenance contracts in place for quarterly maintenance and annual validation of washers and autoclaves.
- Patients will receive a high standard of care through use of sterile RMD that has followed a process which is able to be tracked, audited and does not compromise on the health and safety of patients. (Health and Disability Commission 2019)
- The external reviewers were presented with three questions prior to the review.

- The review team believe that the questions have been answered without blame being placed to any one HBDHB staff member. Rather there were several failures that led to this event.

CONCLUSION

Hawkes Bay District Health Board and staff are to be commended for making open disclosure on this event. The work that the Hawkes Bay District Health Board review team undertook, in particular, the identification and follow up clinics for the potentially affected patients was completed in a timely, professional and systematic process, ensuring that all patients were informed and supported. There are lessons to be learnt not only for HBDHB but for every DHB in New Zealand as well as for the Ministry of Health.

The reprocessing of RMDs and sterile services within our health care environments has for too long been ignored by the health service management due to it not being a source of revenue, but rather requiring high cost investment. However, patient safety within New Zealand should be the number one priority.

It is recommended that going forward that the Ministry of Health should note that for all DHB's in New Zealand the following should occur immediately to prevent further incidents occurring:

- Electronic tracking and traceability systems should be installed in all sterile service units and operating theatres as soon as possible, tracking down to individual instrument level.
- Within 18 months tracking should be extended out to include all RMD used in wards and outpatient clinics.
- Annual auditing of CSSD/SSU departments against the standard AS/NZS4187:2014 is performed by an external auditor. This should be in conjunction with a robust internal auditing programme as detailed in the standard.
  Note: A document for auditing against the standard is available. The tool was specifically commissioned and developed by the New Zealand Sterile Sciences Association.

REFERENCES

Australia and New Zealand Sterilisation Standards. (2014). AS/NZS4187:2014 *"Reprocessing of Reusable Medical Devices in Health Care Service Organisations". Australia and New Zealand Sterile Sciences Association. www.nzssa.org (Retrieved March, 2019).*

Health and Disability Commission. (2015). Code of Rights. Health and Disability Commissioner. Wellington. www.hdc.org.nz/disability/the-code-and-your-rights (Retrieved March, 2019).

Health Quality Safety Commission (HQSC). (2019). Surgical Site Infection Improvement Project. Health Quality Safety Commission New Zealand. Wellington. www.hqsc.govt.nz/our-programmes/infection-prevention-and-control/projects/surgical-site-infection-improvement (Retrieved March, 2019)

New Zealand Sterile Sciences Association. (2019). Scope of practice and competencies for Sterile Technicians. www.nzssa.org (Retrieved March, 2019).