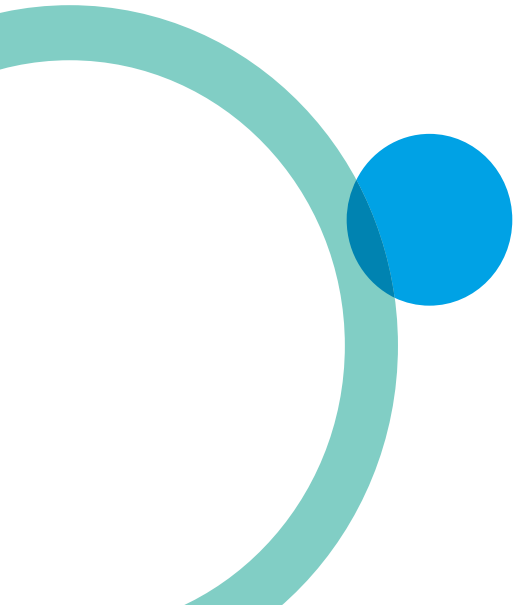
Aberdeen Royal Infirmary - Endoscopy Decontamination Unit

IRIC investigations 825, 826 & 841.

NHS Grampian



June 2018

Contents

Executive Summary

The scope was consideration of a number of IRIC investigations INV 825, 826 & 841. These related to validation matters of their Endoscope Washer Disinfectors (EWDs) within their Endoscope Decontamination Unit (EDU) at Aberdeen Royal Infirmary and Washer Disinfectors within their Local Decontamination Unit in Aberdeen Dental Hospital.

Two of the incidents that took place in 2017 did not have negative impacts on the quality of products delivered to patients, as the relevant chemicals were later proven to pass the validation criteria. The other incident concerning Amity PAA15 used in the EWD 009145 was determined by NHS Grampian Infection Prevention and Control (IPC), that there had been no any adverse exposure to patients.

1. Introduction

1.1 IRIC within Health Facilities Scotland received notice of a number of incidents at NHS Grampian concerning their Endoscope Decontamination Unit (EDU) at Aberdeeen Royal Infirmary (ARI).

Scope

1.2 The scope of investigations as table 1

Reference	Subject
IRIC Ref No: INV825 OCC1019/MHRA Ref No: 2017/006/022/291/007	The use of non-validated disinfectant (Amity PAA15) in Wassenburg Endoscope Washer Disinfector (EWD)
IRIC Ref No: INV826 OCC1020/MHRA Ref No: 2017/006/022/291/009: 007	The use of non-validated detergent (Neodisher Endoclean) in Steelco Washer Disinfector in Aberdeen Dental School and in Wassenburg Endoscope Washer Disinfector
IRIC Ref No: INV841 OCC1039/MHRA Ref No: 2017/007/024/291/004	Delayed annual validation and temperature setting of Wassenburg Endoscope Washer Disinfector (EWD) 2017

Table 1: Chemical incidents reported to IRIC in 2017.

2. Review of incident - IRIC Ref No: INV826 OCC1020/MHRA Ref No: 2017/006/022/291/009: 007

2.1 This was concerned with the use of incorrect detergent (Neodisher Endoclean) in Steelco Washer Disinfector in Aberdeen Dental School and in Wassenburg Endoscope Washer Disinfector in Endoscope Decontamination Unit (EDU). Endoclean was purchased and stored in the cabinet as it was believed to be simply a rebranding of the existing MediClean Forte.

Situation

2.2 On 13 June 2017, the contractor (Medical Devices UK) found the non-validated detergent (Endoclean) was used in Steelco DS600 washer disinfectors (WD) located in Aberdeen Dental Local Decontamination Unit (LDU).

In addition, 5 bottles of trial detergent (Endoclean) was also found to be used on the EWDs located in Aberdeen Royal Infirmary (ARI) EDU. Endoclean was stored in the storage cabinet in EDU along with other process chemicals.

Background

Wassenburg EWD in ARI EDU

2.3 MediClean Forte had been validated for the use in Wassenburg EWDs in EDU. For example, the annual validation for cleaning efficacy test of EWDs on 19th February 2017 demonstrated MediClean Forte 42ml dosing, 5 minutes 10 seconds contact time at 38.15oC produced satisfactory results.

Steelco WDs in Aberdeen Dental LDU

2.4 Aberdeen Dental LDU installed Steelco WDs and MediClean Forte was validated to be used as detergent for these machines. The purchased chemicals were ordered and delivered to Central Decontamination Units before transferring to LDU. Aberdeen Dental LDU was closed due to refurbishment.

Analysis

Steelco WDs in Aberdeen Dental LDU

2.5 The Endoclean was procured in the belief that this was simply a rebrand of MediClean Forte. During the time of Endoclean was placed in WD and the time of discovery, the WDs were not used to process instruments due to the refurbishment of the decontamination unit. NHS Grampian confirmed no instrument was processed in Steelco WD using Endoclean.

Wassenburg EWD in ARI EDU

2.6 During the period of incidents, endoscopes were subjected to manual pre-cleaning followed by cleaning and disinfection process in automated EWDs despite using the chemical previously has not been validated for these machines.

2.7 On August 2017 the cleaning efficacy test of Endoclean on 8 EWDs on-site were undertaken, in accordance with HTM 2030, by Medical Devices UK. The testing parameters (i.e. temperature, time and concentration of detergents) were in the same range (e.g. as those used routinely including during incident on early June 2017. The results of the cleaning efficacy test on endoscopes found satisfactory (. This demonstrated Endoclean has similar cleaning performance as MediClean Forte and was able to satisfactorily clean the endoscopes in EWDs setting during the incident. Thus the risk on patients due to this incident was minimal. However, it is always advised the validation must be carried out prior to use.

Recommendations

2.8

- to develop change management process covering stages from planning, review, approval, implementation (procurement, training, execution) and post-review. This may cover trial and proposed change of chemicals, other consumables, equipment, facilities etc. It's recommended to involve the appropriate specialist (depending on products/services) e.g. in decontamination, procurement, infection control/microbiologist, AE(D), estates/facilities, risk, medical physic etc;
- to specify the chemical name, temperature and contact time and other cycle in the reference document e.g. SOP or Work Instruction and training material.(if any) This information should be made available for the staff carries out the relevant duties;
- to check the items against the reference documents prior to purchase, distribution, receipt on-site and prior to use;
- to improve storage of chemicals and others i.e. not to store the items which are not used within the units or secure restricted access;
- to complete change chemical form and signed by supervisor;
- to obtain a written confirmation from the manufacturer that the brand name has been changed and that the chemical compositions and other physical chemical characteristics remain the same as the original product;
- even in the case where the chemical name has been simply rebranded, the label on the cabinet should be changed with the new name.

Conclusion

2.9 Based on the records reviewed, over the three days examined, it is concluded that manual wash of the endoscopes was taking place.

3. Review of incident - IRIC Ref No: INV825 OCC1019/MHRA Ref No: 2017/006/022/291/007

3.1 This was concerned with the use of incorrect disinfectant (Amity PAA15) in Wassenburg Endoscope Washer Disinfector (EWD).

Situation

3.2 On 13th June 2017, it was found the non-validated chemical disinfectant (Amity PAA15) was used in EWD Wassenburg 009145 located in Foresterhill EDU. The chemical change form was not completed, the last recorded chemical change in EWD 009145 was 2nd June 2017 and the date of discovery was 13th June 2017.

3.3 Eleven endoscopes were processed on EWD 009145 on 12-13 June 2017. Ten of them (ID No 876030-GI; 987130-GI; 876044-ITU; 053-GI; 876029-GI; 061-ECC; 015-GI; 987016-Community; 130-Ward 202; 987241-Rach) were recalled. Endoscope ID no 987130-Ward 209 could not be recalled and had been used on a patient.

Background

3.4 Disinfectant Neodisher SeptoPac was the disinfectant validated for use for all Wassenburg EWDs in EDU.

On 31st May 2017 Medical Devices UK carried out a trial of new chemical disinfectant (Amity PAA15) on EWD Wassenburg 009140.

Amity PAA15 was stored in the chemical cabinet in EDU with the label ‘Do not use. MDS to advise’ at one side of the bottle. Other process chemicals were also stored in this cabinet. On 13 June 2017, Amity PAA 15 was found being used on EWD 009145 instead of SeptoPac. High volume of PAA 15 was left in the bottle after being removed from EWD 009145.

Analysis

3.5 During the period of incidents, endoscopes were subjected to manual pre-cleaning followed by cleaning and disinfection process in automated EWDs despite using the chemicals previously have not been validated for these machines. Both SeptoPac and Amity PAA contain the same active ingredient i.e. peracetic acid.

3.6 Based upon the low volume of Amity PAA15 used in the EWD 009145, NHS Grampian was confident only few endoscopes were processed using Amity PAA 15. Eleven endoscopes processed on 12 and 13 June 2017, ten of them were successfully recalled. According to NHS Grampian Infection Prevention and Control (IPC), there is no reason to believe there has been any adverse

exposure to patients. Health Protection Scotland was notified by NHS Grampian with a green classification in the Healthcare Infection Incident Assessment Tool.

Recommendations

3.7

- to develop change management process covering stages from planning, review, approval, implementation (procurement, training, execution) and post-review. This may cover trial and proposed change of chemicals, other consumables, equipment, facilities etc. It's recommended to involve the appropriate specialist (depending on products/services) e.g. in decontamination, procurement, infection control/microbiologist, AE(D), estates/facilities, risk, medical physic etc;
- to specify the chemical name, temperature and contact time and other cycle in the reference document e.g. SOP or Work Instruction and training material.(if any) This information should be made available for the staff carries out the relevant duties;
- To check the items against the reference documents prior to purchase, distribution, receipt on-site and prior to use.
- To improve storage of chemicals and others i.e. not to store the items which are not used for the decontamination process in the appropriate location or secure restricted access.
- To complete change chemical form and signed by supervisor.
- to ensure there is no unauthorised product kept in the facility including to make arrangements with the contractor to remove the products, after each use, from the facility.

4. Review of incident - IRIC Ref No: INV841 OCC1039/MHRA Ref No: 2017/007/024/291/004

4.1 This concerned the delay of annual validation and temperature setting of Wassenburg Endoscope Washer Disinfector (EWD) 2017.

4.2 The eight Endoscope Washer Disinfectors (EWD)s were subject to their annual validation by Health Facilities Scotland (HFS) on February 2017 following up to eight weeks delay from previous year. On 2014 and 2015, the annual validation of EWDs were carried out on January, they were brought forward 2-4 weeks earlier on December 2015 or early January 2016 to fit in with the engineer schedule. Due to staff leaving the post and sickness, the delay of annual test could not be avoided on 2017.

4.3 However, the EWDs had received 4 quarterly tests with the last one in November 2016 indicated satisfactory results. They also received a quarterly test in February 2017 with satisfactory results, at approximately the same time as the HFS annual validation.

4.4 Immediately on completion of the validation tests on February 2017, the Competent Person (Decontamination) [CP(D)] verbally confirmed that all EWDs were "satisfactory" without the need for remedial actions, this was recorded in each EWD log book. The microbiology reports from Andersen Caledonia were received in March/April 2017. There was a minimum 8 log reduction on all surrogates inoculated with Pseudomonas aeruginosa, Staphylococcus aureus, Candida albicans and Bacillus subtilis. All final rinse water tests for TVC, hardness, conductivity; Mycobacteria etc. were also satisfactory.

4.5 The full annual validation reports were sent to NHS Grampian on 13th June 2017, stating the satisfactory results for all parameters of annual test for all EWDs. However, On July 2017 the HFS Authorising Engineer Decontamination [AE(D)] provided feedback on the test report concerning the disinfection temperature setting. AE(D) identified a number of Wassenburg WD440 baths had failed to attain 25°C x 10min required for Dr Weigert Septo-PAC disinfectant and were taken out of use pending resolution. NHS Grampian reported to IRIC same day 7 July (OCC1039).

4.6 NHS Grampian EWDs had been set to commence dosing at 21°C and start disinfection timer at 23°C since commissioning and rely upon agitation in bath to attain 25°C, however due to cold RO water supply the required 25°C x 10min not always achieved.

4.7 Dr Weigert responded on 11 July to confirm their recommended temperature x contact time is 25°C x 10min. It is also stated that disinfectant must not be used at 23°C as there was no type test (log reduction) data to support lower temps.

4.8 On 10 July AE(D) recommended (in agreement with Medical devices UK and NHS NHS Grampian) that disinfection start parameter should be increased >25°C to ensure 25°C x 10min achieved regardless of incoming RO temperature – this was based on newer versions of WD440s having higher temperature parameters than those at NHS Grampian. All agreed this was safest and simplest way forward.

4.9 On 12 July Medical Device UK (MD UK), the third party contractor, made required parameter changes (minimum disinfection temp 25°C) and revalidated (thermometric tests) 12-13 July – AE(D) review 18 July thermometric tests satisfactory, with follow up for IMS data which likewise reviewed satisfactorily 21 July.

4.10 On 19 July IRIC investigation INV841 commenced. AE(D) discussed with the manufacturer of disinfectant i.e. Dr Weigert and the manufacturer of EWD i.e. Wassenburg regarding discrepancy between Dr W's recommendations for SeptoPAC and Wassenburg's parameters.

4.11 On 19 July AE(D) was informed that MD UK had also increased disinfection temperature parameters at Dr Grays; AE(D) recommended thermometric tests should similarly be carried out to prove disinfection temperatures – however these were not done since annual tests (June) were satisfactory.

4.12 On 26 July AE(D) reviewed commissioning tests dated Feb/March 2011 for the NHS Grampian WD440s which revealed a number of issues: several baths did not achieve disinfection 25°C x 10min, but there was also significant variation from one machine to another – several <25°C whereas others operated closer to 30°C disinfection, there were also significant variations ~5°C between Left/Right baths on same machine with no explanation, and test equipment had not been calibrated for range in use. Subsequent annual tests by HFS have been satisfactory except for the 2017 tests under scrutiny where supply RO temperature appears to have been colder, however micro surrogates have been satisfactory throughout.

4.13 On 2 Aug NHS Grampian returned all baths into use following acceptance of July's thermometric tests by MD UK and AE(D) reviews.

4.14 On 10 October in response to IRIC investigation INV841 / OCC1039 Wassenburg Regulatory Affairs wrote to NHS Grampian and stated that they would not take responsibility for the WD440s at NHS Grampian since the parameter changes had been made by MD UK which is not authorised agent of Wassenburg.

4.15 On 11 Dec Wassenburg Regulatory Affairs stated that they had commenced new type tests of SeptoPAC <25°C with lower water supply temperatures to simulate NHS Grampian conditions – this work because original data from NHS Grampian no longer available at Wassenburg.

4.16 On 6 March 2018 type test results received from Wassenburg Reg Affairs confirming satisfactory disinfection efficacy, although acknowledging this is outwith recommended temp x time stated by Dr Weigert for SeptoPAC - and claim that they can waive requirements of ISO 15883-4, clause 5.5 because of

their new type test data (requirement 5.5 ‘The conditions of use (temperature, concentration etc.) within the EWD for all process chemicals (detergent, disinfectant etc) shall be within the limits specified by the process chemical manufacturer’).

4.17 WD440s at NHS Grampian were re-programmed July 2017 by Medical Devices UK to adopt disinfection parameter settings of newer WD440s and ensure 25°C x 10min – The view of NHS Grampian’s AE(D) (and agreed NHS Grampian and MD UK) is that this was the logical and safest action, and ensures that the machines will disinfect at temp x time recommended by chemical manufacturer, irrespective of supply water temperature. It also removes any regulatory argument around requirements of 15883-4, clause 5.5. Satisfactory disinfection temp x time was verified by revalidation thermometric tests with new parameters.

Conclusions

4.18 New type tests carried out by Wassenburg 2017/2018 confirmed satisfactory disinfection efficacy at lower water supply temperatures, and HFS’ microbiological surrogate tests from 2017 and all previous annual tests were satisfactory throughout. This provides assurance that in spite of 2017 annual tests showing <25°C x 10min, the disinfection efficacy was nevertheless satisfactory.

Recommendations

4.19 To increase disinfection temperature parameters ensure that Dr Weigert’s recommended 25°C x 10min is attained for Septo PAC regardless of incoming water supply temperature.