JUNE 2015

The Clinical Services Journal

Delivering savings in endoscope reprocessing

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The endoscope decontamination unit at Croydon Health Services NHS Trust has recently implemented changes which have delivered annual savings of £56,000. *The Clinical Services Journal* reports.

Left to right: Gareth Jones, Audere Medical Services; Peter Brown, Croydon Health Services NHS Trust; Matthew Peskett, Peskett Solutions.

The Croydon Health Services NHS Trust's endoscopy unit sees approximately 11,000 patients a year, performing diagnostic and therapeutic procedures such as oesophageal-gastro-duodenoscopy, colonoscopy, bronchoscopy and endoscopic-retrograde-cholangio-pancreatograph (ERCP). The reliability of the Trust's endoscope reprocessing services and efficient turnaround of scopes between procedures are crucial to meeting increasing demand and ensuring patient safety.

Peter Brown, general manager of decontamination, medical equipment and commercial development at the Trust, was seeking to appoint a servicing, maintenance and validation company capable of improving the availability of endoscope washer disinfectors (EWD), increase uptime and reduce the time taken to obtain validation reports. At the same time, the endoscope decontamination unit decided to evaluate alternatives to proprietary chemistries, previously used.

After contacting various suppliers, one of the six EWD chambers was removed from circulation and the new alternative chemistries were tested and validated, following the guidelines of the *Choice Framework for Local Policy and Procedures (CFPP) 01-06, Decontamination of flexible endoscopes: operational management, section 4 (Process Chemicals)*.

Peter Brown explained that CFPP 01-06 states that the EWD manufacturer should offer at least three different disinfectants and detergents suitable for their EWD. However, in reality this rarely happens.

Although endoscope manufacturers can provide a list of 'approved', compatible products, this is by no means exhaustive, since it is costly for the medical device companies to test the huge variety of chemistries available. In fact, not all EWD manufacturers' own chemistries are listed as 'approved' by the endoscope manufacturers. Peter Brown decided to conduct independent testing, therefore.

Implementing changes

A risk assessment was carried out and a stakeholder group established – which included the external Authorising Engineer (Decontamination), the senior infection control nurse, a consultant microbiologist, as well as Peter Brown, in his capacity as decontamination lead.

Following an evaluation by the Trust, one of the largest independent maintenance and validation organisations within the UK, Audere Medical Services, was selected for the servicing, maintenance and revalidation of the EWDs. Peskett Solutions, a distributor of detergent and disinfectants for reprocessing medical devices, was chosen for its expertise on the supply of alternative chemistries.

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"Throughout the process, patient safety was our primary consideration. We went through the CFPP guideline step-by-step – looking at the quality of the water, the parameters of the machine with the new chemicals, and the results of microbiological testing," Peter Brown explained.

Meeting the CFPP requirements

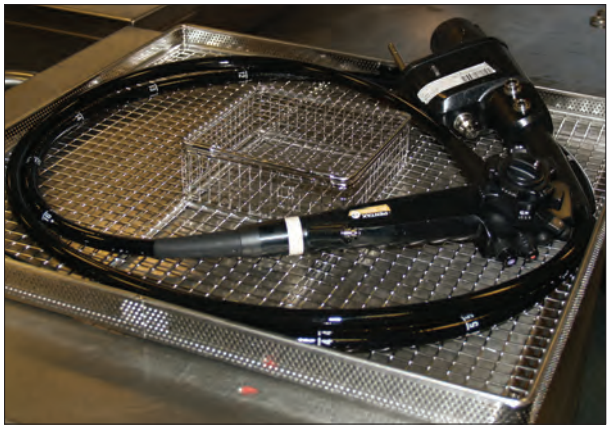
Each of the requirements of the CFPP 01-06 document (section 4) were considered, then the required action was taken and evidenced. The CFPP 01-06 states that: 'Harm to endoscopes may result from some processing chemicals. The reprocessing instructions supplied by the manufacturer should be followed carefully.' The Trust's endoscopes are from Pentax and the manufacturer's instructions state: 'If you would like to change the products [i.e. chemicals] you use, we strongly recommend that you contact the manufacturer of the reprocessing chemicals to obtain suitability.'

The Trust followed this recommendation and Peskett Solutions was instructed to ensure chemical compatibility with both the machine and the endoscopes, providing assurances (and insurance) that if the machines or the endoscopes were damaged the Trust would be compensated. The new chemicals were also required to be CE Marked.

The CFPP guidance further states that: 'The EWD control settings need to match

the chemicals used'. To address this, the control settings were adjusted to match the dilution rates of the new chemicals and this was performed by Audere's EWD 'manufacturer trained' engineer.

Audere Medical Services, which uses accredited, independent company Andersen Caledonia for microbiological testing, ensured the EWD was put through annual validation testing. The microbiological tests included:



- Surrogate devices.
- Biofilm.
- Water testing including total viable count (TVC), endotoxin and mycobacteria.
- Full chemical analysis and chemical residual test.

"Every test was well within the limits," said Peter. "There are 13 requirements just for the quality of the water alone. The EWD with the new chemistries passed all of these. These tests are required with all chemistries – even those supplied by the EWD manufacturer. But by performing the tests when the annual validation testing is scheduled, there are no additional costs."

The CFPP guidance also says that 'If the chemicals used in the EWD are changed, care should be taken that the new chemicals do not react with traces or deposits of the previous detergent or disinfectant.' The EWD was flushed through five times with sterile water before adding the new chemistries.

Another requirement of CFPP is that 'During works tests, the EWD manufacturer will determine the parameters for the EWD operation that match the detergents selected for use with the EWD'. This was done by Audere's EWD 'manufacturer trained' engineer. In addition, the guidance states: 'Instructions for use supplied with the disinfectant should include the quality of water with which the product should be diluted'. The disinfectant instructions stiplulate that the water should not have chloride content in excess of 50 mg/L. However, the water result was 0.4 mg/L and was therefore a 'pass'.

Results

"This project has saved the Trust around £56,000 per year. All NHS Trusts are facing financial constraints and other sterile services departments have been watching what we are doing here closely," Peter Brown commented.

"There have been challenges to what we are doing by outside parties, but we have been able to provide evidence to the Trust Development Authority that we are following published CFPP guidance, which states that you can change the chemistries that you use, and we were able to provide data to show that the safety of the process will not be compromised. After a 45 minute conversation, the decontamination lead for the TDA was satisfied," he continued.

It was a stipulation of the decontamination unit that Audere Medical Services would ensure that the most common spare parts were stocked and replenished on site, at the Trust. This has contributed to an increase in uptime for the EWDs as they can be serviced much quicker. Validation reports are now made available electronically to the Trust, via Cloud technology, within 48 hours of completion of the tests.

"The fact that EWD uptime has increased also shows that the chemistries have been changed with no detriment to the machine," added Gareth Jones, director, Audere Medical Services. In addition there have been no issues with chemical damage to the scopes and reports by Pentax have been positive.

Other benefits, following the project, have also been reported as Peter Brown explained: "For health and safety reasons, we perform gas detection monitoring and we have not had to evacuate the department since making these changes."

He commented that a key factor has been the introduction of a new leak detection method, called a 'Ground Hog' unit. This provides an earlier indication of a leak occurring and shuts off the pump as soon as any moisture is detected. The unit has reduced its risk in relation to the Control of Substances Hazardous to Health (COSHH), therefore.

Discussion

"My advice to other Trusts is to first establish whether there is a requirement to change, to test the market to see if there are more affordable solutions, and to look closely at the requirements of the CFPP document. It is also vital to ensure that you risk assess what you are trying to achieve first, setting out the desired outcomes and using all the standards and guidance available.

"Forming a stakeholder group is also crucial – the stakeholder team was comfortable with the processes I put forward, before we started to do anything. It is about trying to get the Trust to understand the issues that you have and the potential benefits. It is also important to feedback updates on the project and to present the final data to the stakeholder team to sign off."

"Patient safety is often mentioned, but the Trust has been able to evidence that the alternative chemistries do not pose a risk," commented Matthew Peskett, managing director at Peskett Solutions. "The issue of type testing has also been suggested as a potential barrier to changing chemistries, but this can be performed on site. There is nothing in the EN regulations or CFPP to say that it has to be factory type tested – you just have to ensure compatibility. The alternative chemistry is a proven, tried and tested formula – in this case a mild-alkaline detergent and a Peracetic acid for disinfection."

"EWD manufacturers' type tests may be performed outside of the UK, and may not take into account the quality of the water in this country – so local testing and validation, on site, are very important," added Peter Brown. "There is a need to test the chemicals against the scopes that you use, and in your locality, which is often not well understood."

He went on to point out that manufacturers may also change OEM suppliers of parts (such as seals for example). As factory type testing will not address these variables once the machine is installed, type testing *in situ* at the Trust is crucial in his view.

Conclusion

In conclusion, Matthew Peskett commented: "When you buy a car, you are not dictated to on which brand of petrol you can put in it. It should be the same with the chemistries that you use in your EWD. As long as the chemistries are virtually identical and do not compromise the machine or endoscope, there should not be a problem. There needs to be an open debate."

Peter Brown emphasised that the process was discussed with, and approved by, the senior infection control nurse and consultant microbiologist and no patient risk was identified. The Trust was committed to ensuring that the CFPP guidance was followed and each point was addressed to ensure chemical compatibility with the materials of construction of the EWD and flexible endoscopes being processed. ✚

Delivering Savings in Endoscope Reprocessing

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