Is a lumen really cleaned if you can't see down it?

Marija Juraja, Andrew Ellis
Infection Prevention & Control Unit , Central Sterile Supply Department
Central Adelaide Local Health Network

BACKGROUND

In hospitals every day we use equipment that is cleaned and sterilized, how can we be sure? With modern advances in designing equipment, many used in surgical procedures, contain channels that require vigorous cleaning and brushing to remove bio burden before they are placed through a final sterilisation process. Sometimes though equipment can have design flaws that aren't always evident until months or years later. With any equipment where there is a lumen the assumption is made that the processes undertaken are sufficient and optimal but I challenge that with what we found.

FINDINGS Part 1

In late 2016 a hysteroscopy used in surgical procedures was identified by Central Sterile Supply Department (CSSD) staff as containing a foreign substance when performing a routine clean of the device post procedure. The material that was discovered in the channel could have been any number of substances. The CSSD Manager had provided advise that the scope is processed according to the manufacturers guidelines and after cleaning the scope the CSSD staff hold the scope up to a light source and inspect the inside of the scope with regard to what can be seen at the external opening. This particular scope had been in use since August 2012 and used in 107 procedures. On finding the foreign substance the scope was removed from service and sent to Biomedical Engineering Department (BED).

BED initial investigation found that the scope was intact and no flaking or peeling could be seen. As per protocol the scope was then sent to the manufacturer for further review. A few weeks later the scope returned with a report stating some loose matter was found lodged inside the channel.

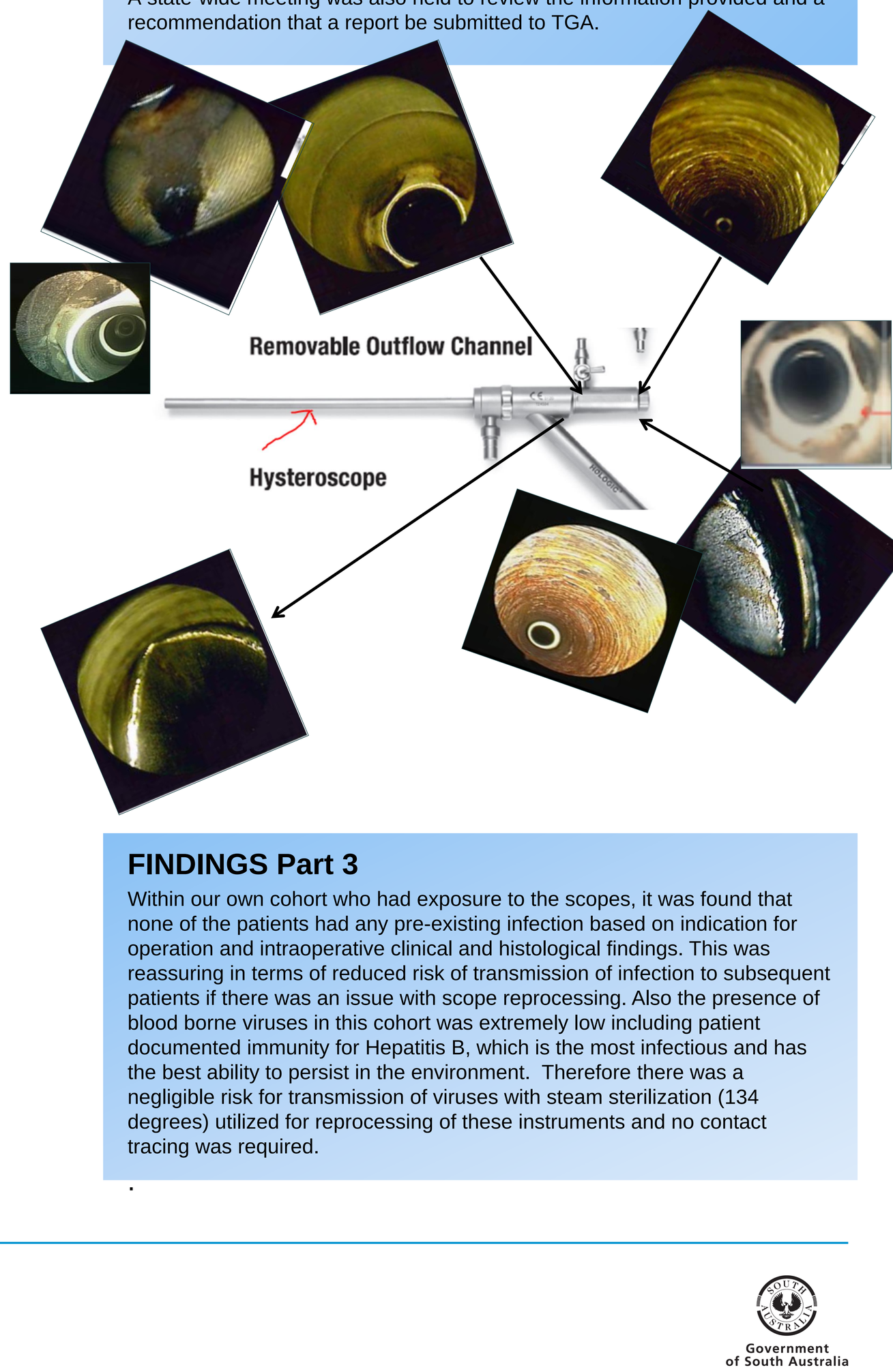
A state-wide meeting was also held to review the information provided and a recommendation that a report be submitted to TGA.

FINDINGS Part 2

With these findings it raised concerns for other similar scopes and whether we would see the same issues, not only for our organisation but for others as we all utilise the same scopes. After some discussion BED sourced a special camera/light source that could visualise the internals to determine whether their hypothesis of other scopes having similar issues was founded.

BED then reviewed 70 & 25 degree rigid scopes from different hospital and with their findings (refer to pictures 1-6) found that the ridges and voids within the scope made the scope difficult to clean. Of particular concern was the rust build up found in some of the scopes, with some scopes less than six months old and in continuous use. On further investigation the scopes had varying issues from an internal polished shaft, a distal tip window that was calcified, rust and foreign particles found within the channel.

The state made a decision that the device removed from use and replaced with an sourced product. As well you can see the media was engaged.



CONCLUSIONS

This highlighted how important our CSSD services are in cleaning and reprocessing devices. It gave us challenges and opened up debate about solid scope designs. It highlighted that we should be undertaking randomised visual inspections of these scopes to validate the cleaning process. This should be included in any assessment of a new scope prior to implementation or even well before this in the design phase.

FINDINGS Part 3

Within our own cohort who had exposure to the scopes, it was found that none of the patients had any pre-existing infection based on indication for operation and intraoperative clinical and histological findings. This was reassuring in terms of reduced risk of transmission of infection to subsequent patients if there was an issue with scope reprocessing. Also the presence of blood borne viruses in this cohort was extremely low including patient documented immunity for Hepatitis B, which is the most infectious and has the best ability to persist in the environment. Therefore there was a negligible risk for transmission of viruses with steam sterilization (134 degrees) utilized for reprocessing of these instruments and no contact tracing was required.

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