REVIEW

What every endoscopist should know about decontamination

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ABSTRACT

Carbapenemase-resistant Enterobacteriaceae (CRE) has been implicated in an alarming increase in the incidence of endoscopy-associated infections and deaths worldwide. Public Health England acknowledges that the rapid spread of CRE bacteria poses an increasing threat to public health and modern medicine here in the UK. As endoscopists, we assume that the endoscope we are handed has been appropriately decontaminated, but how many of us can honestly say that we understand the process and the pathway by which the instruments we use are reprocessed? Do we understand the associated risks if the pathway fails and our part in supporting the teams responsible for this critical role? Successful decontamination of endoscopes is everyone's business, and this article outlines what every endoscopist should know about decontamination.

His conscience was clear and his heart light amidst all his troubles; so he went peaceably to bed, left all his cares to Heaven, and soon fell asleep. In the morning after he had said his prayers, he sat himself down to his work; when, to his great wonder, there stood the Endoscope all ready decontaminated, on the table.

Adapted from *The Elves and the Shoemaker*, Brothers Grimm 1812.¹

INTRODUCTION

Decontamination of endoscopic equipment is still a mystery of the fairy tale variety to many endoscopists, who beyond checking that the instrument is functioning before use pay little heed to, or question the decontamination process that has gone before. Section three of the Health and Safety at Work Act² makes it a criminal offence if a Trust fails to conduct its duty in such a way as to ensure that patients are not exposed to health or safety risks. This is a standard of care with a reverse burden of proof, that is to say

that it would be for the organisation to prove that it did take all reasonably practicable steps to prevent infection and not the patient to prove that it did not. As an endoscopist, we should be assured and reassured that the instrument we are using does not pose a risk to the patient in the knowledge that ignorance would be no defence in law.

WHAT IS THE RISK?

Estimating the risk of infection from endoscopic equipment is difficult as patients may develop infections some time after discharge and not associate it with their endoscopic procedure. The risk of the transmission of variant Creutzfeldt-Jakob disease (vCJD) was sufficient to raise the profile of endoscope decontamination a decade ago, but the decreased incidence in recent years and increased knowledge and guidance³ appear to have relaxed previous vigilance. However, there have been a number of high-profile incidents and cases of infection related to endoscopy that have renewed the awareness of the risk and the subsequent need to manage out that risk. According to Kovalova *et al*,⁴ inadequate decontamination procedures and equipment malfunctions are two leading causes of postendoscopic infection and contamination, more than 91% of which could have been prevented if quality control systems were improved.

The increased worldwide focus on infection associated with endoscopic decontamination has come largely on the back of the United States Food and Drugs Administration (FDA) report,⁵ following an alarming increase in the incidence of endoscopy-associated infections and deaths between 2012 and 2015. The FDA medical device reports show that the number of infections following endoscopic retrograde cholangiopancreatography (ERCP) increased from 8 in 2012 to 15 in 2013 to 64 in 2014 and to 30

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in the first 6 weeks of 2015. Carbapenemase-resistant Enterobacteriaceae (CRE) was the organism implicated and although many of the reported outbreaks have been in the USA, there have also been reports from all over Europe. Although mostly associated with ERCP, CRE has also been implicated following bronchoscopy, gastroscopy, cystoscopy and endoscopic ultrasound. The number of infections is likely to be grossly under-reported with a failure to either look for or report infections.⁶ Public Health England (PHE) acknowledges⁷ that the rapid spread of CRE bacteria poses an increasing threat to public health and modern medicine here in the UK.

Escherichia coli, *Klebsiella* spp and *Enterobacter* spp have all been implicated in infection outbreaks following endoscopic procedures.^{4 8 9} Transmission of CRE results in infections that can remain asymptomatic for many months before manifesting as a clinical infection and therefore may not immediately be linked to a preceding endoscopic procedure thus thwarting identity of the source and prevention of further cases. Clinical infections from CRE carry a 40% mortality rate,⁵ and this should be in every endoscopist's awareness. In England, colonisation of the waste water system in two English hospitals resulted in an outbreak of multidrug-resistant (VIM-producing) *Pseudomonas aeruginosa*,¹⁰ with 85 infections recorded between 2005 and 2011 and 34 deaths.

The transmission of CRE from reported cases in endoscopy can be divided into the following categories:

1. Poor instrument design.
2. Endoscope defects.
3. Inadequate manual cleaning.
4. Inadequate disinfection.
5. Inadequate drying.
6. Poor training and education.

Successful reprocessing of endoscopes should be everybody's business.

So what should every endoscopist know?

Risk

Every endoscopist should understand the CRE risk in their population and ensure that they are taking relevant precautions to mitigate against that risk within their organisation. Local protocols and policies should be followed which includes checking whether within a 12-month period patients have been an inpatient in a hospital abroad or in a UK hospital which has problems with spread of CRE or have themselves previously been a positive case. This is particularly important with high-risk patients and or high-risk procedures. PHE have produced a toolkit for the early detection, management and control of CRE,⁷ including relevant action cards.

The risk posed from other infections including vCJD should not be forgotten; the last reported death from vCJD was in 2016, but there is an increasing incidence of CJD with the highest reported number of deaths yet

in the UK in 2017.¹¹ If undertaking transnasal endoscopy, there is the risk of CJD if olfactory mucosa is breached,³ raising the importance of adequate training of transnasal endoscopists.

Water used in the endoscope washer disinfector (EWD) must be free of particulate contamination and micro-organisms.¹² The final rinse water is sampled from the EWD and tested weekly for its microbiological quality in accordance with the relevant Health Technical Memorandum (HTM). Endoscopists need to be informed where the total viability count exceeds recommended levels and restricts the use of the machine. The decision to continue to use the EWD should be a multidisciplinary team decision based on the clinical risk to patients versus the consequences of cancelling lists.

Decontamination process

Every endoscopist should understand the decontamination process within their organisation, including where it is undertaken and how long it takes to fully reprocess an instrument from bedside clean back into use. Putting pressure on decontamination services to turn around instruments results in poor or incomplete processes, which have been implicated in infection outbreaks.⁴ The most critical step in the decontamination process is manual cleaning which, when correctly done, is made up of more than 30 steps and adequate time needs to be built in to enable staff to undertake this fully. This necessitates sufficient numbers of endoscopes and EWDs to meet service needs, allowing for complete reprocessing and as importantly, planned preventative maintenance. Endoscopists should bear this in mind when setting up additional services or lists. Some useful algorithms for calculating the numbers of instruments required can be found in the Irish Health Service Executive document on standards and recommended practices for designing and equipping endoscopy decontamination units.¹³

Equipment design

Endoscopes are becoming increasingly more complex instruments and as such greater attention to decontamination methods is required. The global outbreak of CRE linked to duodenoscopes was a result of a change in instrument design that was supposed to solve the issue of effectively cleaning and decontaminating the elevator-wire channel which, because of the design, resulted in limited space for fluid to be injected down the channel. The new design sealed this channel completely so that it no longer required reprocessing; however, it meant that the only barrier between the contaminated exterior and the channel was an 'O' ring which cannot be seen or easily replaced by users. In addition, these instruments do not have a removable tip unlike the duodenoscopes used in the UK, largely for litigation purposes in the event that the tip came off during a procedure. This meant that it was almost

impossible to visualise and effectively clean around the tip. Coupling instrument design with both high-risk patients and procedures created a perfect maelstrom for infection.

Although these instruments are not used in the UK, it is important that no endoscope is procured and/or put into operational use unless the organisation is fully satisfied it can be decontaminated to UK standards.

EWDs are complex and highly technical pieces of equipment. They are designed to monitor key variables as part of the automatic reprocessing cycle. Such monitoring regimes can be a source of frustration; however, experience shows that monitoring can pick up scope damage, lack of channel irrigation as part of cleaning, obstructions within channels and so on. They are configured to enhance patient safety and, in combination with the manual clean, provide a device safe for re-use on subsequent patients. However, they too have been subject to design issues that when coupled with human factors led to a failure to effectively decontaminate endoscopes. This occurred in one Trust in 2014,¹⁴ where the design of the EWD allowed the disinfectant and its corresponding activating solution to be used interchangeably resulting in a failure in the decontamination process and the recall of 357 patients. Reprocessing must be undertaken by competent staff in a timely manner with documented processes that allow for the tracking and traceability of every step of decontamination right back to the patient in the event of a breach in process or integrity of equipment. Validation of EWDs is required at periodic intervals in line with national guidance (HTMs) to verify that the equipment achieves the decontamination criteria required within the UK.

Over recent years, technologies have become available to store endoscopes for extended periods post reprocessing within the EWDs. Such systems can be a drying cabinet, specifically designed to store the scope within a controlled environment that meets standards of national guidance; alternatively, they can be stored in vacuum-packed systems that are designed to protect endoscopes in a controlled manner and time period. Endoscopists should be aware of how endoscopes are stored and satisfy themselves that the systems in use have been validated. This means that if a manufacturer states that their cabinet allows endoscopes to be stored in a decontaminated state for 72 hours that this has been validated by the organisation.

Training and education

The Health Act first published in England in 2006¹⁵ stipulates the roles of decontamination leads and decontamination programmes. It emphasises the need for staff to be trained in decontamination processes and to hold appropriate and validated competencies for the role they undertake. A move from registered nurses undertaking decontamination within endoscopy units to technicians and increasingly the move

of facilities to central sterile services or off site led to a temporary decline in standards, largely due to the employment of staff with no prior infection prevention knowledge or experience and poor provision of appropriate training or education. This is a dedicated role that must be undertaken by staff appropriately trained in decontamination techniques and aware of the individual anatomy of each scope that requires reprocessing. There has been a focus on the provision of training in this area and endoscopists should ensure that out of sight does not mean out of mind where the competence of this workforce are concerned as they are an integral part of the endoscopy team and should be given the same opportunities to attend relevant training.

Training programmes for endoscopists should include an understanding of the process for the decontamination of endoscopes and the rationale behind all the steps in the process.

Assessment of ongoing risk

Decontamination should be a standing agenda item at user group meetings (EUG) to support ongoing clear visible governance of processes from the individual in the decontamination room up to the chief executive of the organisation. This will ensure that there are clear up-to-date policies and an audit programme to maintain consistent standards. Audits should be fed back to endoscopists and actions identified and supported to fruition. Decontamination representation should be at EUG meetings and teams should be involved in any planned expansion to activity within endoscopy units, including the planned purchase of any new endoscopic equipment that increases the workload of decontamination facilities, requires different decontamination methods or requires different connectors or adaptors to be able to reprocess them successfully. As an example, when using colonoscopes to undertake whole lists of flexible sigmoidoscopy procedures, the turnaround of instruments can quickly become insufficient to allow the smooth running of lists because decontamination staff are used to a slower turnaround of these instruments when used for colonoscopy. The result is increased pressure on staff and an increased risk of poorer adherence to manual cleaning processes, which are a critical step in the decontamination cycle.

Managing out risk

Endoscopists should look out for alerts or advisory notices posted through the British Society of Gastroenterology online portal. These are written with input from a group of experts forming the Decontamination Professional Expert Communication Forum, which comprises the chairpersons of all the leading decontamination societies in addition to representation from industry. A frequent challenge to these is that they can appear to be using a sledgehammer to crack a nut. However, evidence suggests that human factors lead to

errors and therefore the rationale is to manage out all risk associated with lapses in practice where possible.

The authors suggest that the endoscopist is responsible for wiping down the exterior of the endoscope before handing it to the assistant to minimise the risk of transferring infection between personnel, and there is now a move to minimise that risk even further by asking the endoscopist to complete the bedside clean. We await the reception to this idea with some trepidation.

The Joint Advisory Group focus on improving safety and reducing error in endoscopy must recognise and include the error and safety risks within decontamination as the lynch pin of endoscopy services. Decontamination staff must feel encouraged and empowered to raise issues where the safety of processes are threatened, which increase the risk to patients every time an instrument is used.

CONCLUSION

Decontamination is everybody's business and not just that of elves secreted away in back rooms. CRE alone is a real and present risk in the UK, with increasing public awareness of the risks. When combined with the imperative to undertake more and increasingly complex procedures on sicker patients, it is no longer satisfactory for endoscopists to abrogate all responsibility for at least understanding the pathway by which the instruments we use are reprocessed. Additionally, we must be seen to be supporting the teams that are responsible for the process, to ensure that they are given the resources, time and training to provide the service safely and competently.

Finally, if you find yourself going peaceably to bed with all cares to heaven and yet still cannot sleep, you can always read the HTM guidance on the management and decontamination of flexible endoscopes.¹⁶

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