

Endoscope Disinfection

- The case for national regulations -

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Key points

- Although the use of flexible endoscopes has transformed treatment strategies for many diseases, patients are often unaware that these procedures carry an increased risk of cross-contamination.
 - Automated endoscope reprocessing has taken a significant role in reducing the level of exposure to toxic disinfectants for nurses and other healthcare workers but it has not been eliminated. Many hospitals are also continuing to use aldehydes that are widely known to fix vCJD prions and other bioburden to endoscopes.
 - Advisory bodies and working parties abound in the sector, yet several recent health scares and alerts suggest that guidelines issued are failing to address long-standing safety issues. The case for sharing best practice and developing national regulations is compelling.
 - An existing regulatory body must be empowered to effect immediate change in order to address identified safety issues, or alternatively a new regulatory organisation with clearly defined legislative powers should be created and tasked with the same remit.
 - Additional strategies to be considered include: improving training standards within the sector; banning aldehyde-based disinfectants; replacing multi-shot disinfectants with single-shot solutions; and agreeing a workable and effective standard for final rinse-water.
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Endoscope disinfection – the case for national regulations

Flexible endoscopes have transformed the diagnosis and treatment of a wide sector of health issues, especially gastrointestinal, lung and urinary diseases, but patients are often unaware that the procedure carries a potential infection threat. These risks are escalating as techniques become increasingly invasive and with more patients with multiple diseases and/or immune system deficiencies being endoscoped than ever before. Yet a recent study by the Patients Association looking at endoscope disinfection practices within NHS Trusts in England found that only 32% of respondents discussed infection control matters with their patients [Patients Association, 2004].

Although automation has had a major impact in limiting nurse and other healthcare worker exposure to toxic chemicals, it has also meant that many hospitals have decided to continue using chemicals that are either known to or are capable of causing significant health problems. Glutaraldehyde (glut) is still used by some units and a number of alternative chemicals that the British Society of Gastroenterology (BSG) has highlighted as potential skin and respiratory sensitisers requiring the same handling precautions as glut are also used extensively in our hospitals [BSG, 2003].

The problem is exacerbated because decisions on which disinfectant to use, or the most appropriate reprocessing methodology, are often taken locally whilst macro issues such as the safety of patients and employees working in the sector require a more effective strategic approach designed to share learnings, experience and best practices. In 2004, the MHRA issued two MDAs relating to endoscope disinfection practices and the case for national regulations has never been more compelling [MHRA, 2004 a, b].

This article examines four areas that could have a significant impact on improving patient and healthcare workers' safety: audited training standards; banning the use of aldehyde-based disinfectants; replacing multi-shot with single-shot disinfectant solutions; and agreeing an achievable standard for final rinse-water.

Procedural errors carry the greatest risk

The greatest risk factor for endoscopy-induced infection arises either from damaged instruments or from procedural failures such as incorrect preparation of the disinfectant solution, contaminated rinse water, or simple connection errors within the automated endoscope reprocessor (AER) [BSG, 2003]. Automation is now standard but audited and on-going training for all staff members involved in the process is essential to avoid operator errors.

A recent case in Northern Ireland demonstrates how quickly a simple but unchecked error can escalate into a major health scare. By the time the connection error was identified, up to 15 endoscopes had been used on over 3,000 patients. The risk that the endoscopes may not have been disinfected properly was high, therefore each patient had to be contacted and advised that they may have to undergo blood tests for HIV, hepatitis and other viral diseases [Press Association, 2004]. This scare prompted the MHRA to issue an MDA highlighting two areas of particular concern: use of the wrong connection sets to connect endoscopes to the AERs, and inadequate disinfection and rinsing of auxiliary channels that were not used during the procedure [MHRA, 2004 b].

Aldehydes fix vCJD prions

Although the operator health problems associated with glut are well known and it is listed by the HSE as one of the main causes of occupational asthma [HSE, 2004], the chemical continues to be used routinely as a first choice disinfectant by some UK hospitals. The number of hospitals is undoubtedly in decline but some alternative disinfectants that have been introduced may not be as safe as first thought; there may be a second wave of occupational injuries to come.

The BSG's guidelines, published in 2003, suggested that while ortho-phthalaldehyde (OPA), peracetic acid and chlorine dioxide are all less irritant than glut, they are nonetheless potential skin and respiratory sensitisers. The report recommended using the same handling precautions for these chemicals as for glut including fume extraction/containment and personal protective equipment [BSG, 2003].

However one of the most significant patient health risks from glut and OPA is not related to their irritant or sensitising properties but their ability to fix vCJD prions. Aldehydes are known to denature prions making them more adherent and therefore harder to remove from contaminated surfaces even with steam sterilisation [Taylor, 2004].

Manual pre-cleaning, prior to disinfection, is the most important step in removing prions from endoscopes [Axon et al, 2001] but there is still a theoretical risk that they can be carried over into the disinfection phase. To address this, the UK's Department of Health has stressed that aldehyde-based disinfectants should not be used for any procedure on known, suspected or undiagnosed vCJD patients [DoH, 2003].

While the size of the potential sub-clinical population is still under active debate, many hospitals are managing this hazard by treating all endoscopy patients as potential vCJD 'carriers' and therefore the continued use of aldehydes by any hospital in this application cannot be justified.

Two additional points also support this view:

- The sub-clinical vCJD population may be significantly higher than first thought, and the UK government's ban excluding 50,000 blood donors who have received transfusions since 1980 from acting as donors reinforces this [DoH, 2004].
- vCJD infectivity is known to proliferate in the nervous and lymphatic tissues and in theory upper gastrointestinal tract procedures bring endoscopes into contact with lymphoid tissue. The tonsils are known to concentrate prions and some gut lymphoid tissue may be only one cell thickness away from the gut lumen. In addition, every day the intestine sheds huge numbers of superficial epithelial cells or the cells can become disrupted by the endoscopic examination itself [Axon et al, 2001; David Taylor, personal communication].

Multi- versus single-shot disinfectants

The recommended protocol for some current disinfectants is for repeated re-use until the solution's biocidal activity against a reference range of micro-organisms drops below a certain level. Some solutions may be re-used for up to 14 days and/or to reprocess 40 or more endoscopes. This methodology, as opposed to preparing a fresh solution for each patient, cannot be justified when attempting to minimise the vCJD infection risk amongst an unknown population. It is possible that prions could become concentrated to the point that the disinfectant solution becomes a 'soup of prions'.

David Taylor, an acknowledged international expert on vCJD and member of the UK's Department of Health Decontamination Group said, "If you are trying to reduce the risk of accidental vCJD transmission then it seems common sense to use single-shot solutions for endoscope reprocessing rather than re-using the same solution for multiple patients."

Multi-shot disinfectants can reduce the cost per reprocessing cycle but with so much still to be uncovered on the aetiology and pathology of vCJD it would seem sensible to minimise the transmission risks by mandating against multi-shot disinfectants.

Generating bacteria-free rinse water

The final stage in the automated reprocessing cycle is to rinse the disinfected scope free of any remaining disinfectant. Sterile water could be used but it is prohibitively expensive and therefore considerable effort has been channelled into making mains water safe for the final rinse. The NHS Estates' HTM 2030 guidelines attempted to set out clear specifications on the quality of water needed but the requirements are confusing and there is growing concern within the sector that the recommendations are expensive to implement and maintain [NHS Estates, 1995].

The results of a recent four-month study involving 20 UK endoscopy units confirmed that hospitals are struggling to achieve consistently the HTM 2030 guideline of zero colony-forming units per 100 ml of rinse water. 62% of samples studied were not bacteria-free and there was no common policy on how and when to react to poor microbiological results. The authors suggested that future guidelines would be more helpful if they recommended practical approaches and a scale of remedial actions depending on the bacterial counts found in contaminated water samples [Willis, 2004].

In an attempt to simplify the issue, a joint HIS/PHLS working group was set up to provide clearer advice on the cleaning and disinfection of processors including the maintenance and disinfection of rinse-water pipework plus any recommended or applicable filters. The authors have also confirmed disparate practices regarding microbiological monitoring of rinse water and what actions should be taken to combat biofilm build-up within the automated reprocessor and associated pipework [HIS, 2004].

Patients are clearly at risk here because processed scopes can and are re-contaminated during the final rinsing stages of the reprocessing cycle and there are many published reports on resultant outbreaks and pseudo-outbreaks involving *Legionella*, *Pseudomonas*, and *Mycobacterium* species [HIS, 2004]. The costs, health risks and damage to the hospital's reputation in dealing with an outbreak are considerable and yet many hospitals are unaware of what action to take when finding their rinse water feed is contaminated.

Hospitals would benefit considerably from implementing clearer and more practical regulations for maintaining and monitoring a rinse-water supply.

Conclusions

Flexible endoscopy has transformed the prognosis for many patients and conditions that previously required costly, in-patient, surgical intervention can now be treated faster, at lower cost and more effectively. But most patients are unaware that their procedure carries an infection risk. The risks are also rising from increasingly invasive practices and with more patients, often with multiple diseases and/or immune system disorders, being endoscoped than ever before.

Automation has helped protect endoscopy staff from routine exposure to toxic disinfectants and introduced more consistent reprocessing but it has increased the potential health threats for patients.

Aldehyde-based chemicals, known to fix vCJD prions, are still being used and simple operator errors when using sophisticated AERs have been shown to quickly escalate into large-scale health alerts involving a significant number of patients.

There are guidelines, review bodies and multiple examples of best practice across the country but there is no one body pulling all of this together into a coherent infection control strategy for the endoscopy sector. The case for a national legislative body with the power to enforce regulations is compelling and the time is now. There is often also an attitude that exists that believes guidelines are only guidelines and the advice given does not need to be followed.

-ENDS-

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