Recommendations for the decontamination of endoscopes

for Otorhinolaryngology, Head and Neck Surgery, 2017

Andrew C. Swift

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Decontamination of flexible endoscopes

Decontamination of flexible endoscopes and rigid endoscopes 2017

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Key Points

1 Following flexible endoscopy of the upper respiratory tract, the endoscope will need to be cleaned and decontaminated to an acceptable standard according to the Health and Technical Memorandum HTM 01-06 policy guidelines (revised March 2016). Rigid endoscopes are not covered by this document.

2 It is most important to clean and remove residual mucus, blood and debris from the endoscope after use, prior to sending for decontamination. This can be effectively achieved by hand with soap and water.

3 Chemical decontamination utilising wipe systems, such as chlorine dioxide, are acceptable should an Endoscopic-Washer Disinfector (EWD) be unavailable. This system should only be carried out according to a set protocol by staff fully trained in the technique.

4 Most hospitals have now introduced central decontamination models to minimize the risk of cross infection. For hospital that are still considering to change to this model, the hospital board should be aware of the significant cost implications of the central decontamination model.

5 Every hospital or clinic should maintain a robust system of individual endoscope traceability in place and ensure that regularly audit takes place

6 It is acknowledged that endoscope contamination with prions remains a serious potential risk.

7 Should endoscopy be done on patients with suspected or known vCJD, the current advice from the DH is that the endoscope should be quarantined until the patient's vCJD status is known. If the patient is proved subsequently proved positive, the endoscope should then be destroyed according to the recommended protocol as set out in HTM 01-06.

8 Endoscope sheaths are not considered to provide sufficient protection in vCJD patients.

9 Hospitals should consider having disposable flexible endoscopes available for use in patients with vCJD. Each endoscope costs approximately £200 each and are currently undergoing further development.

10 All endoscopes should be identified and tracked; they should undergo regular planned maintenance and decontamination issues should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) via their website

1 Introduction

1.1 Background to the Regulations

The official guidance for endoscope decontamination was established in 2004, following a decontamination incident with a flexible gastrointestinal endoscope in Northern Ireland that triggered a survey in the Province. The Medicines and Healthcare products Regulatory Agency (MRHA) issued MDA/2004/028 - 'Flexible and rigid endoscopes' on 23 June 2004, and an Endoscopic task Force was set up in England.

This led to the publication of the Choice Framework for local Policy and Procedures (CFPP). This was superseded by the Health Technical Memorandum (HTM) publication in 2012.

The Health Act Code of Practice recommends that healthcare organisations comply with guidance ensuring Essential Quality Requirements (EQRs) that encompasses all existing statutory and regulatory requirements. It is understood that this will enable organisations to demonstrate that a plan is in place to progress to Best Practice.

The guidance was developed specifically for flexible endoscopes, largely based on endoscope use in gastroenterology and respiratory medicine. The current documents include some reference to flexible endoscopes being used within our specialty, but these apply to flexible fibreoptic nasendoscopes only. Rigid Hopkin's rod endoscopes are not included in the official guidelines.

1.2 Recent changes

Since the initial ENT UK guideline document, published in 2010, the Department of Health has updated their policy document on the decontamination of flexible endoscopes in March 2016 (Health Technical Memorandum: HTM 01-06).

The DH update was published to take account of the recent changes to the ACDP-TSE (Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies) Subgroup's general principles. The Subgroup's guidance was updated in May 2015 and is now being continually updated.

The documents aim to reflect the need for continuously improved outcomes in terms of patient safety, clinical effectiveness and patient experience.

All healthcare organisations now have in place Infection Prevention and Control (IPC) teams and decontamination managers who will impose their own interpretation of the official guidelines, thus leading to significant differences in practice throughout the UK.

1.3 *The justification for central decontamination units*

The NHS governance system demands that endoscopes are decontaminated properly using a standardized quality assured system.

The gold standard followed by NHS Trusts is central decontamination within designated decontamination units. This approach aspires to Best Practice as encouraged by the HTM document, but also aims to minimise the risk of cross-contamination.

The actual risk of cross contamination is extremely low, but the concept of minimising risk is a response to the potential risk of the transmission of prion-related disease and its consequences. This also introduces the concept of Corporate Risk.

The minimization of risk by central decontamination is expensive and requires the purchase of adequate numbers of rigid and flexible endoscopes to maintain a clinical service.

1.4 *Current decontamination systems*

The endoscope decontamination systems include:

- chemical cleansing wipe systems
- single use endoscope sheaths
- endoscope washer-disinfectors (EWD)
- autoclave sterilization

The latter 2 methods require a central decontamination unit. Both have high cost implications and can seriously impact on the delivery of clinical services.

A popular alternative to central decontamination is the chlorine dioxides wipe system. The chlorine dioxide system is much less expensive but deemed an inferior method of decontamination. The system requires staff to be fully trained and conversant with the technique but introduces the risk of human error.

1.5 *Transmissible spongiform encephalopathies (TSEs)*

Prion diseases are rare but fatal neurological disorders that can be sporadic, genetic or acquired. The commonest human prion disease is sporadic Creutzfeldt-Jakob disease (sCJD). In the UK there are 50-60 cases annually, with a peak incidence in the 60-70 year age group. Sporadic CJD presents with rapidly progressive dementia, with other neurological features, leading to death in 3-6 months from the onset.

Genetic human prion disease accounts for about 10% of the total number of cases and acquired, including iatrogenic and variant CJD, account for 1% of the total. Whereas the incubation period of variant CJD varies from 2 to over 40 years, the abnormal prion has been detected in lymphoid tissue prior to the onset of the clinical signs and symptoms.

In sporadic CJD, the abnormal prion is restricted to the central, nervous system, whereas in the acquired variant CJD, the abnormal prion has been detected in lymphoid tissue, including the tonsils, spleen and gastrointestinal lymphoid tissue.

The total number of deaths from definite or probable vCJD in the UK, as of 2016, was 177. Three appear to have been acquired from packed red cell transfusion from infected donors, but, non were known to have been caused by transmission by surgical instruments or endoscopes.

Prion protein is considered transmissible because of the following factors: sCJD has been transmitted by neurosurgical instruments used in the brain; abnormal prion protein binds avidly to steel surfaces and is difficult to remove from surgical instruments; prion infectivity has been found in various tissues, including brain, spleen, tonsil and lymphoid tissue.

Prion protein is heat-stable and extremely enzyme resistant. Prion protein is also extremely hydrophobic and once dried on endoscopes and surgical instruments, it is very difficult to remove or inactivate by conventional decontamination processes.

Alcohol or aldehyde-based disinfectants will bind or fix prion protein onto endoscope surfaces.

There are about 5000 people within the UK who have an increased risk of CJD because of a previous surgical operation or medical intervention. The current population of the UK is approximately 65 million people.

Decontamination and management of an endoscope that has been used in a patient within the 'at-risk' group should follow the guidance contained within the specific section of the HTM 01-06 document.

Because of the association of prions residing in neurological tissue, and the central connections of the olfactory receptors, an additional factor is introduced with regard to the use of flexible endoscopes within the nose.

Olfactory epithelium is deemed of medium infectivity. Should an endoscope be used in a patient with increased risk of vCJD, the subsequent actions should be determined by the actual risk of contamination by olfactory epithelium, according to the advice of the 'consultant' carrying out the endoscopic procedure (the guidance document specifically refers to the term 'consultant'). If contamination cannot be excluded, then appropriate precautions must be taken.

1.6 *Endoscope decontamination in ENT practice*

Endoscopes that are passed into the upper respiratory tract will be contaminated by mucus, saliva and in some cases blood. The risk of cross-contamination applies to bacteria, fungi, spores, viruses and also residual biofilms that may adhere to endoscopes. It is therefore good practice to ensure that each endoscope is thoroughly cleaned before use on another patient.

Whilst there is a definite clinical need to prevent cross-infection, the risk of cross-infection and harm resulting from this remains low. However, the consequences of prion transmission are serious.

There is no national guidance or policy with regard to the decontamination of rigid endoscopes. The management of rigid endoscope decontamination is determined by the local hospital policy. Since rigid endoscopes are now made to withstand autoclaving, many units apply this standard of quality and control.

The HTM 01-06 guidance applies only to flexible endoscopes. Because most ENT endoscopes do not have biopsy channels, the HTM 01-06 guidance has a special section on the decontamination of flexible endoscopes.
(please refer to Health Technical Memorandum 01-06: Decontamination of flexible endoscopes. Part C: Operational management, paragraphs 3.60 to 3.64)

This current guidance document aims to summarise the key points of the DH manual, and to highlight the areas of current controversy and uncertainty. The information is restricted to that deemed to be most useful and practical for colleagues in clinical practice in Otorhinolaryngology, Head and Neck surgery, and is not designed as a comprehensive summary of the whole HTM document.

2 Key Points from HTM 01-06 for the management of nasendoscopes

Essential Quality Requirement must be applied as outlined within the HTM document, but there are some specialty specific exceptions that apply to flexible nasendoscopes without lumens:

2.1 Decontamination processes

2.1.1 Endoscopes without lumens can be manually decontaminated using validated wipe systems.

2.1.2 The distance between some ENT clinic areas and a suitable decontamination unit is acknowledged. Manual methods of decontamination are therefore acceptable.

2.1.3 Manual methods should include efficient cleaning, followed by controlled wiping or immersion in an effective, compatible disinfectant.
If immersion is used, non-immersible components need to be disinfected as well. Cleaning and disinfection are also required after single-use sheaths.

2.1.4 For cannulated endoscopes with lumens, the endoscope should be processed in a central reprocessing unit with purpose-designed EWDs. If this is not possible, the endoscope should be decontaminated in a smaller reprocessing unit operating to the same standards as a central unit.

2.1.5 Decontamination staff should be trained on how to decontaminate the specific type of endoscopes that are being reprocessed.

2.1.6 A leak test should be performed on each flexible endoscope prior to decontamination, irrespective of the method of processing. An automatic leak test is performed by most EWDs but a manual test should also be done at the end of the cycle.

2.2 Endoscope Storage

2.2.1 Decontaminated non-lumened nasendoscopes should be stored in a clean, secure area, such as a cabinet or cupboard made of non-porous easy-to-clean material.

2.2.2 There is no maximum time for storing non-lumened nasendoscopes as it is acknowledged that bacterial contamination will not replicate in the absence of liquid water.

2.2.3 There are two possible storage options for nasendoscopes with lumens such as biopsy channels:

- *Storage cabinets*
  A secure cabinet that keeps them away from contamination but does not dry the endoscope. The endoscope should be sent for reprocessing if more than 3 hours elapses between decontamination and clinical use.

- *Controlled environment storage cabinets*
  Endoscopes stored in a cabinet that passes clean area around the endoscope and through the lumens will dry the endoscope, prevent bacterial replication and preserve their decontaminated status, irrespective of time.

2.3 *Endoscope packaging and transport*

2.3.1 If the decontaminated endoscope is to be used in an adjacent room, care will be needed to prevent contamination en route.

2.3.2 Should the decontaminated endoscope need to be transported to another part of the hospital, it will need protection from contamination and potential damage. Systems are available that utilize a specific tray with a plastic liner, covered by a plastic sheet and a solid cover.

2.3.3 Transport between an EWD and a drying cabinet should be as short as possible to prevent biofilms from forming in the residual water. Once dried, the biofilm growth will stop.

2.3.4 If endoscopes are decontaminated in a plastic container that serves as a process chamber and a carrier, the storage life is limited to 3 hours.

2.3.5 The time of processing should be recorded on the endoscope package so that transit time can be checked, as storage time is an important determinant of contamination.

2.4 *Tracking, traceability and audit trail*

2.4.1 The emergence and possibility of transmissible spongiform encephalopathies (TSEs) is a key factor in underlining the importance in tracking and traceability of individual endoscopes and their use in individual patients.

2.4.2 It is essential for healthcare organisations to operate a system that demonstrates each part of the decontamination process has been carried out effectively for each endoscope. This should identify the complete life cycle of each unique endoscope during each part of the process.

2.4.2 It is also necessary to identify each patient who comes into contact with the unique endoscope. Each endoscope should have a unique identifier.

2.4.3 The system should be tested to ensure that it can handle likely events effectively.

3 Specific guidance for endoscopes used in patient with or suspected of having vCJD, according to HTM 01-06

The key area of controversy of this section arises because of the presence of olfactory mucosa within the nasal cavity and the assumption of contamination by contact with olfactory mucosa.

The actual detail of the guidance document states that for non-invasive endoscopic procedures, the advice of the 'consultant' performing the endoscopy should be sought as to the likelihood of contamination. If the risk of contamination by olfactory epithelium cannot be excluded with confidence, then precautions for 'medium infectivity tissues' should be applied.

The term 'contamination' is not defined within the document and is open to differences in interpretation. Mucus secreted from the olfactory epithelium is not secreted directly from olfactory receptors, and logically, should not contain prion protein. The olfactory mucosa is largely protected within the olfactory cleft but the absence of discrete margins, particularly on the middle turbinate, leads to uncertainty. The author suggests that 'contamination' should mean breach of the olfactory mucosa rather than simple contact.

Single-use disposable endoscopes are available and should be used where possible within this group of patients. These endoscopes have been designed for bronchoscopy but are currently being developed specifically for nasendoscopy and should be available in 2017.

Precautions advised for flexible nasendoscopy with possible, suspected or known infection with CJD:

3.1 Asymptomatic patients:

3.1.1 *Known increased risk of CJD*
No special precautions necessary, unless contamination by olfactory mucosa cannot be excluded.

If contaminated by olfactory mucosa, the endoscope should be destroyed or quarantined for further use on the same index patient

3.1.2 *Presumed to be infected with CJD*
Destroy endoscope after use or quarantined for further use on the same index patient

3.2 Symptomatic patients:

3.2.1 *Presumed to be infected with CJD or diagnosis unclear*
Quarantine pending confirmation of diagnosis

3.2 *Definite of probable variant CJD*
Destroy endoscope after use or quarantine for further use on the same index patient

3.2 *Definite of probable sporadic CJD, iatrogenic CJD or inherited prion disease*
Destroy endoscope after use or quarantine for further use on the same index patient

Appendix 1

Details on specific methods of decontamination

1 Chemical disinfection

Several chemicals have good disinfection properties. These include chlorine dioxide (Tristel), hypochlorous acid / superoxidised water (Sterilox) and peracetic acid (Steris, Nu-Cidex, Persafe, Gigasept, Dopsidex). Peracetic acid is irritant to skin and the respiratory system.

Glutaraldehyde is no longer in use as it carried high risks of inducing sensitivity.

This section is restricted to a description of chlorine dioxide since this is a popular choice of disinfecting agent in many ENT clinics throughout the UK.

Chlorine dioxide wipes (Tristel)

The chlorine dioxide system has 2 components for disinfection: impregnated wipes and foam that is generated from a can with a nozzle. The foam is added to the impregnated wipe.

The system provides a rapid manual cleansing system applicable to both rigid and flexible endoscopes. A strict protocol should be followed.

The endoscope is initially washed in soap and water before being wiped with the chlorine dioxide impregnated wipes. The endoscope is then rinsed in water and dried. The process takes about 2-3 minutes.

Once disinfected, the endoscope should be placed in a clean plastic bag or covered lined transport tray that is appropriately labelled.

Activity of chlorine dioxide

The chlorine dioxide system is active against vegetative bacteria, mycobacteria, fungi, viruses and spores.

Chlorine dioxide has been shown to be effective against *Mycobacterium terrae* to demonstrate tuberculocidal activity.

Chlorine dioxide has specifically been shown to be active against hepatitis C virus and HIV after 30 seconds of contact time.

The chlorine dioxide wipe system system is approved by market leaders who manufacture rigid endoscopes.

Advantages

- The system is simple, quick and effective and offers a traceability system.
- Endoscopes can be decontaminated within the department
- The system is relatively inexpensive: the cost of cleaning each endoscope is just over £4.00, excluding the person time
- Debris can be removed from the endoscope whilst it is still moist.
- Staff can be easily trained in how to use the system and the protocol is easy to follow.
- The risks to hospital staff are remote.

Disadvantages

- Clinical support staff will need to be fully trained and conversant with this technique
- The system requires manual cleansing of the endoscope and this is perceived as introducing an additional risk factor
- The decontamination process is often performed by the clinic staff and this could impinge on clinic support

2 Disposable sheaths

Sheaths have been available for covering flexible endoscopes since the 1990's but early designs were not always easy to apply and remove and also affected the optical image provided by the endoscope. However, these technological problems have now been improved.

The sheath system has been shown to be a safe and effective alternative to chemical disinfection systems. Sheaths are effective against bacterial and viral contamination and have been shown to maintain their integrity after patient use.

Following patient-use, the endoscope should be cleaned by an enzyme detergent, rinsed with water and wiped with 70% alcohol. The latter is recommended just in case there is ever a breach in the sheath during use.

Advantages

- The sheath systems are generally quick and easy to use

Disadvantages

- There is a very small risk of endoscopic contamination if the sheath is breached.
- There are occasional difficulties experienced in sheath removal
- Bacterial contamination of the control head of flexible endoscopes must be considered during the cleansing process as a sheath does not cover this area.

3 Endoscopic Washer disinfectors (EWD) for flexible endoscopes

Automated mechanical washers are designed for decontaminating flexible endoscopes. Prior to placing into the machine, the endoscope needs to be manually cleaned with a biological enzyme agent impregnated into a sponge.
EWDS can decontaminate 2 endoscopes simultaneously during each 40 minutes cycle. Once the endoscope has been through the washing cycle, it should be placed in a specific sterile plastic bag and tray for transport to the clinic.

Advantages

- The model facilitates a standardised decontamination program
- A report on each cleansing cycle can be generated for audit purposes
- Each endoscopic incident can be accurately logged for traceability
- If central decontamination facilities exist, the responsibility for standards and audit of decontamination are devolved to the decontamination unit
- Clinic support staff no longer need to spend time decontaminating endoscopes and should be available for greater clinical support

Disadvantages

- The specialised washing machines require space and either a separate room for installation or a central decontamination unit
- They machines require maintenance and filters require regular changing
- Decontamination staff need to be specifically trained to operate and maintain the EWDs
- The turnaround time is relatively slow and sufficient endoscopes need to be available to maintain a clinical service without causing unnecessary delays
- The decontamination process may decrease the clarity of the optical image within a short period of time. Endoscopes will therefore need to go for refurbishment on a regular basis

4 **Autoclave sterilization for rigid endoscopes**

Endoscope sterilization is only possible by using an autoclave. Rigid endoscopes are now made to withstand this process.

Advantages

- The risk of cross contamination of patients should be reduced to an absolute minimum.

Disadvantages

- A large number of endoscopes will need to be purchased or leased
- The supply of sufficient numbers of sterile endoscopes needs to be sufficient to maintain clinical throughput of patients
- There will be an increased need for maintenance and repair
- Dry debris may remain on the endoscope after sterilization if the endoscope has not been cleaned prior to autoclaving

Appendix 2

Definitions of terms

Sterilization
An endoscope is sterile when all living microorganisms on its surfaces have been destroyed. This includes bacteria, spores and viruses.

Disinfection
This is the process of killing infectious agents and microorganisms that can cause infectious diseases.

The process may involve disinfecting agents or physical processes. A disinfectant is an agent that destroys disease-causing microorganisms and their spores.

Decontamination
The use of physical or chemical means to remove, inactivate, or destroy blood borne or other pathogens on a surface of an endoscope. The surface is technically not sterile, but any contaminants are rendered safe and no longer capable of transmitting infectious particles

Spaulding Classification applied to Endoscopy

Classification	**Type of Procedure**	**Appropriate Level of Decontamination**
Critical	Invasive device enters tissue that is usually sterile or enters the vascular system. This includes contact with breaches in the skin and/or mucous membrane	Sterilization
Semi-critical	Device contacts intact mucous membrane but does not penetrate sterile tissue;	High level disinfection Sterilization preferred where practicable
Non-critical	Device only contacts intact skin	Cleaning (and low level disinfection where necessary)

Appendix 3

Useful tips on the practical management of an endoscopic decontamination service

Healthcare organisations must make important decisions with regard to their preferred systems for the decontamination of both rigid and flexible endoscopes. Individual organisations will need to take into account various factors including expenditure and maintenance of clinical services in making their choices.

1 The hospital must have sufficient numbers of flexible endoscopes to support a central decontamination model.

2 The logistics of keeping the clinic supplied with clean endoscopes must be planned and organised. This will include turn-around endoscopic processing time and safe transport in a timely manner back to the clinic.

3 The number of endoscopes required should ideally be based on **maximum** and not average use per clinic session.

4 The predicted number of endoscopes to service a clinic should be multiplied by **1.5** to make allowance for inevitable breakage, wear and tear.
It is estimated that a third of the endoscopes will need to be sent away for repair or refurbishment at any one time, although this number will fluctuate and vary between individual units.

5 A maintenance program should be planned to ensure that clinical services run to optimum efficiency. This planned expenditure should be included within the annual budget.

6 Where a central decontamination endoscope processing system is in place, a backup plan for manual decontamination should be in place to cope with unforeseen episodes of high demand or factors leading to decreased supply or turnaround of decontaminated processed endoscopes.

7 It is recommended that each ENT surgeon should acquire personal knowledge of how to assess the optics and light carriage of both flexible and rigid endoscopes. *This will enable constant assessment and maintenance of endoscopes and a steady turnover, avoiding crises where all of the endoscopes become seriously dysfunctional in close succession to each other.*

8 If possible, keep a supply of single-use disposable endoscopes available for unexpected emergency use.

Useful contacts:

Tristel Solutions Ltd:	mail@tristel.com
Ambu: disposable single use endosopes	www.ambu.com

Access to previous ENT UK survey on Endoscope decontamination 2009
http://www.surveymonkey.com/s/endoscope_decontamination_ENT_UK

Author: Andrew C. Swift
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