



at The Royal College of Surgeons of England
35-43 Lincoln's Inn Fields
London WC2A 3PE

Tel: 020 7404 8373 Fax: 020 7404 4200
Email: admin@entuk.org Web:
www.entuk.org

Guidance on the decontamination and sterilization of rigid and flexible endoscopes

**Andrew C Swift
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Key Recommendations

- 1 Following rigid and flexible endoscopy of the nose and throat, the endoscope will need to be cleaned and decontaminated to an acceptable standard. At present the acceptable standard remains undefined and rests with individual hospitals.
- 2 It is most important to clean and remove any residual mucus, blood and debris from any endoscope that has been used in the nose and/or throat. This can be effectively achieved by hand with soap and water.
- 3 Chemical decontamination by chlorine dioxide has been widely used by many hospitals for several years and episodes of cross infection have not been reported. However, this system should be carried out according to a set protocol. There is no reason to discontinue this practice given the current state of knowledge.
- 4 Hospitals may still prefer to introduce central decontamination models to minimize the risk of cross infection. This is an expensive option and the hospital executive board members should be aware of the recurring costs involved before committing to this decision.
- 5 Whatever method of decontamination is chosen, there should be a robust system of endoscope traceability in place.
- 6 It is acknowledged that endoscope contamination with prions remains a serious potential risk but in the general population the risk is probably extremely low.
- 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.
- 8 Currently, endoscope sheaths are not considered to provide sufficient protection in vCJD patients.
- 9 New, disposable flexible endoscopes that cost approximately £250 each should be available
- 10 There is no evidence to show that chlorine dioxide and/or sheaths lead to a greater risk of cross infection compared to processing endoscopes in central decontamination units. The use of chlorine dioxide and/or sheaths should therefore be allowed to continue, even if used as a backup alongside central decontamination systems.

Guidance on the decontamination / sterilization of rigid and flexible endoscopes

Introduction

There has been increasing demand to minimise all risks of infection within the NHS. The decontamination of endoscopes has therefore come under scrutiny.

There is currently no UK uniform system for decontaminating endoscopes used in ENT practice. There is thus much variation in “acceptable” practice for the cleansing of endoscopes in both the NHS and private hospitals.

Within ENT practice, guidance is required for three types of endoscope: rigid Hopkins rods, flexible nasendoscopes (including video-endoscopes) and flexible nasendoscopes with biopsy channels.

The current guidelines for endoscope decontamination have been based entirely on the standards set by gastroenterology, where endoscopes with biopsy channels are passed into the gastro-intestinal tract. However, most endoscopes used within ENT do not have biopsy channels and are not passed into highly contaminated areas.

The greatest fear with regard to cross contamination is a prion-related disease such as vCJD. None of the decontamination systems, including autoclaving, is 100% effective at eradicating prions, but the risk of inducing disease is likely to be extremely low. However, the cost of processing endoscopes in a central decontamination unit is extremely expensive compared to the use of existing chemical wipes and sheaths.

Current decontamination systems

The infection control systems currently available include: chemical cleansing systems, endoscope sheaths, dedicated mechanical washing machines and autoclave sterilization.

The inevitable gold standard that large NHS Trusts support is central decontamination within designated decontamination units. This is because of their focus on minimising risk at all costs. Once one trust goes along this route, others will follow suite. However, this perceived minimization of risk is also the most expensive pathway for hospitals to take, and will require the purchase of a large supply of both rigid and flexible endoscopes.

The least expensive is the use of chlorine dioxides wipes. This method has been used nationally for several years in many hospitals without any reported episodes of cross infection. The chlorine dioxide system is deemed inferior to central decontamination for various reasons, not least being the fact that an individual carries responsibility for washing the endoscope thoroughly and wiping down all surfaces. However, there is no proof that any patient has suffered any harm from this process.

Although several hospitals will already have committed themselves to central decontamination, the current financial situation within the country and the NHS means that funds have to be used wisely to ensure that other services do not suffer as a result of hospitals being over-diligent in their risk analysis of infection control.

Aims and Objectives

The aims of this document are to provide information that should hopefully facilitate sensible but informed choices to be made on the decontamination of endoscopes in Otorhinolaryngology, Head and Neck surgery.

The document is categorized into 3 sections for ease of reference:

Section A lists a series of pertinent clinically useful questions and answers

Section B provides information on the methods of endoscope decontamination and the standards that must be achieved.

Section C summarizes the key points with regard to the various decontamination models and the consequences for hospitals.

SECTION A

Relevant questions and risk analysis for ENT clinicians

1 Have there been any reported instances of an infection being introduced by endoscopy of the upper respiratory tract?

There is no reported evidence to link the introduction of infection with endoscopy of the upper respiratory tract. This is true of both solid rigid endoscopes and flexible endoscopes.

2 What is the likely risk of prions being present within the nose?

The overall risk of prions being carried within the ENT population is likely to be extremely low.

The theoretical risk of contamination of an endoscope by prions being present within olfactory mucosa on the surface of the middle turbinate in an asymptomatic patient has been raised. This risk is not proven and remains hypothetical.

There is a risk of endoscopes being contaminated by tiny amounts of blood in a small number of patients. This is most likely in patients who undergo endoscopic nasal toilet after recent endoscopic sinus surgery. The risk of contamination from endoscopy is still likely to remain extremely low and highly improbable.

3 What action should be taken if an endoscope is used within the nose in a patient with suspected or known vCJD?

The DH amended its recommendations in January 2010. Should an endoscope be used in a patient with suspected vCJD, the endoscope must be placed in quarantine until the condition is excluded. If the patient is subsequently shown to be positive for vCJD the endoscope should be destroyed.

Sheaths are not considered to offer sufficiently robust protection in this situation.

A recent much cheaper alternative is the use of a disposable flexible endoscope (~£250) Disposable endoscopes are now available for purchase and hospitals should be advised to keep some in stock.

4 Is it always necessary to have endoscopes freely available within ENT practice?

The clear answer to this is that the risk of missing serious pathology such as tumours of the nose and throat is very real and highly likely if the correct endoscopic equipment is not available. This risk far outweighs the hypothetical risk and

extremely low probability of transfer of infection from an inadequately cleaned or contaminated endoscope to a patient.

5 Is there any evidence to suggest that the chlorine dioxide wipe system is ineffective?

There is no evidence to show that a risk exists after following the protocol for endoscope cleansing and disinfection with chlorine dioxide. As long as hospital personnel are properly trained in performing and adhering to this protocol, the risk of an endoscope being contaminated is extremely low.

6 Is there a risk of damaging flexible endoscopes during decontamination?

The chemicals used in some automated mechanical washers may significantly impair the optical image of a flexible endoscope; this effect is even more noticeable if the image is displayed on a monitor and could result in the mis-diagnosis of important pathology.

7 Should all rigid endoscopes undergo autoclaving after being used in clinic?

Although autoclaving ensures an ultimate standard of endoscope cleanliness and minimise any potential risks of decontamination, this expensive option necessitates the purchase of large numbers of endoscopes for each hospital. These endoscopes will have a shortened life span and the number of breakages is likely to be high, thus maintaining a substantial burden on hospital finances.

It has been suggested that this process should also include the flexible light lead for each endoscope, where these are not integral to the scope. The infection of a patient from a light lead in the outpatient setting is highly improbable and the purchase of large numbers of leads appears quite unnecessary.

8 Why should flexible endoscopes that have been removed from storage within a drying cabinet be sent for a repeated cycle of decontamination within 3 hours?

This recommendation of a 3-hour time frame was introduced with the initial guidelines on endoscope decontamination (2005) as a sensible suggestion for ideal clinical care since clinics were thought to be completed after 3 hours.

The suggestion of a 3-hour time limit has since been mis-interpreted and applied as a rule that has no scientific basis. If this recommendation is rigidly applied at present, when most clinics are based on a 4-hour time period, the clinics will inevitably run short of endoscopes. Common sense should prevail and endoscopes should be sent for decontamination only at the end of a clinic session.

SECTION B

National requirements for endoscope cleansing / decontamination / sterilization.

Endoscopes that are passed into the upper respiratory tract will be contaminated by mucus, saliva and in some cases blood. It is therefore good practice to ensure that each endoscope is thoroughly cleaned before using on another patient.

There is a definite clinical need to prevent cross-infection. The risk of cross-contamination applies to bacteria, fungi, spores, viruses and also residual biofilms that may adhere to endoscopes. The potential for cross contamination with MRSA and the remote risk posed by prion-related conditions must be given particular consideration. The reported risk of cross-contamination is extremely low, but in reality, events may go unrecognised or may not be recorded

In the modern health service, it is therefore imperative that endoscopes are decontaminated properly using a standardized quality assured system.

Definitions as applied to endoscopes

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

What are the ideals of endoscope decontamination and infection control?

- 1 To minimize the risk of cross-contamination and introduction of infection
- 2 To have a standardized, reproducible effective system
- 3 To ensure that endoscopes are readily available throughout an ENT clinic.
- 4 To ensure that the function and optics of the endoscopes remains at its optimum with repeated endoscope use and cleansing.

Standards of decontamination / sterilization

A review of the literature shows that using an endoscope in the head and neck / upper respiratory tract has not led to a single reported case of cross-infection. Nevertheless, stringent standards of decontamination must be accepted and applied wherever possible.

The standards for decontamination of flexible endoscopes are described in national guidelines developed under the auspices of gastroenterology. These protocols have been designed to be very stringent because of the degree of contamination that these endoscopes are exposed to and the fact that these endoscopes have biopsy channels. Hospital Trusts accept and apply these guidelines to all flexible endoscopes, irrespective of specialty or whether they have biopsy channels.

Endoscope decontamination requires 'process mapping' that must be carefully considered in setting up the models of practice. The process consists of several key stages that include: pre-cleaning, cleaning, disinfection, inspection, sterilization, transport and storage.

Traceability

Once an endoscope has been used on a specific patient, the event should be recorded, noting details of the specific endoscope used within the patient's medical records. This is good clinical governance and useful for patient safety. It is also necessary for future audit.

Should a problem with cross infection ever arise, the pathway of use for that particular endoscope will be clearly traceable. Remedial action can then be instigated and checks made to ensure that other patients who may be potentially at risk are investigated and treated appropriately.

Good standardized decontamination or preventative programs will also be essential defence for hospitals in any future incidents where alleged cross-infection is claimed to have occurred.

Available methods of endoscope decontamination

Rigid endoscopes:

- chemical disinfection systems such as chlorine dioxide wipes
- disposable sheaths
- sterilization in an autoclave

Flexible nasendoscopes:

- chemical disinfection systems such as chlorine dioxide wipes
- disposable sheaths
- standardised mechanical wash after cleansing by enzymatic sponge

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 minutes.

Once disinfected, the endoscope should be placed in a clean plastic bag 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.

Advantages

- The system is simple, quick and effective and offers a traceability system.
- Endoscopes do not leave the department
- The system is relatively inexpensive: the cost of cleaning each endoscope is just over £4.00
- 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 using this system are remote.

Disadvantages

- The system requires manual cleansing of the endoscope and this is perceived as introducing a risk factor that is avoidable.
- The decontamination process is the responsibility of the clinic staff and this usually impinges on clinic support

This model of decontamination has been approved by market leaders who manufacture rigid endoscopes.

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 Automated Endoscope Reprocessors: AERs 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. Each machine 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 climate controlled drying cabinet. The endoscope can be stored here for 72 hours before there is a need to reprocess it again in another decontamination washing cycle.

Once removed from the drying cabinet and placed in a specific transport tray for use in clinic, current recommendations allow for a 3-hour time limit before the endoscope is required to undergo another decontamination cycle. These restrictions must be considered in planning process before instigating this model into clinical situations.

The recommendations for the decontamination of flexible endoscopes is currently under review by the Department of Health

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 decontamination is devolved.
- Clinic support staff no longer need to spend time decontaminating endoscopes and should be able to remain in the consultation room

Disadvantages

- The specialised washing machines require space and a separate room for installation.
- They machines require maintenance and filters need to be regularly changed.
- Hospital staff will need to be specifically trained to operate and maintain the machines. This problem is resolved with a central decontamination unit.
- The turnaround time is slow and enough endoscopes have to be available to maintain a clinical service without causing unnecessary delays.
- The washing 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.

Cost implications

Should hospitals choose this option, it is probably to their advantage to centralize the decontamination process. The optimum standards and consistency for clinical governance and risk management are therefore ensured.

This decontamination model creates 2 important logistical problems that must be addressed in order to maintain clinical services:

- 1 The hospital must have sufficient numbers of flexible endoscopes
- 2 The logistics of keeping the clinic supplied with clean endoscopes must be planned and organised

Although this model ensures that optimum standards are maintained, there are major cost implications that must be factored in. The model will require the purchase of a number of endoscopes, investment in a central decontamination unit and employment of designated staff to transfer endoscopes between the clinic and the decontamination unit, and the purchase and placement of drying cabinets.

Numbers of flexible endoscopes

- The number of endoscopes required should be based on **maximum** and not average use per session.
- The ideal number of endoscopes should then be **multiplied by 1.5** to make allowance for breakages, wear and tear. It is likely that 1/3rd of the endoscopes will need to be sent away for repair or refurbishment at any one time.

A maintenance program should be planned within this model to ensure that clinical services run to optimum efficiency.

4 Autoclave sterilization for rigid endoscopes

Endoscope sterilization is only possible by using an autoclave. Most 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 clinic will need to be supplied with sufficient numbers of endoscopes 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

This model does provide a gold standard for minimizing the risk of cross infection between patients. However, the model induces logistical problems as described above. The following factors should therefore be taken into account:

- The total number of endoscopes must be able to support this model.
- Rigid endoscopes must be readily available within the clinic. Non-availability will induce unnecessary delays that will reduce clinical efficiency.
- The number of rigid endoscopes required to facilitate this model must be based on the maximum numbers used and not average.
- The number of endoscopes that require repair will increase with this model.
- The total number of endoscopes that will be required for this model should be based on the maximum used multiplied by 1.5.
- If central sterilization is off-site, the logistics of timely transport to supply the clinic with endoscopes must be considered in detail.

SECTION C

Summary of key points

Risk analysis

- The risk of cross infection between patients following the use of a rigid or flexible endoscope is extremely remote.
- The recommendation for cleansing endoscopes is based on the perceived risk analysis rather than the actual relative risk of cross infection.
- The actual risk to patient care of not having an endoscope available for clinical use is a much greater problem and could result in the mis-diagnosis of serious pathology.

Chemical disinfection and sheaths

- 1 A large number of hospitals have used the chlorine dioxide cleansing system for a number of years without any reports of undue consequences. There is no evidence to support an increased risk of cross infection with this system.
- 2 An alternative to method of chemical disinfection was to immerse rigid endoscopes into the cleansing solution. This practice can lead to ingress of the cleansing solution into the endoscope. This can lead to serious problems should the endoscope be sent off for autoclaving and the endoscope risks significant damage. The endoscope immersion system and autoclaving are therefore incompatible. There is also a risk to health from immersion fluids.
- 3 Sheaths are effective but are not always easy to use. These are now available for both rigid and flexible endoscopes. However, there are instances where inadvertent damage has resulted to flexible endoscopes during placement and removal of the sheath.

Central Decontamination models

Flexible endoscopes

- 1 Mechanical washing by an automated endoscope reprocessor (AER) in a central decontamination unit is accepted as the decontamination model that minimizes the perceived risk of cross infection for flexible endoscopes.
- 2 Following decontamination of a flexible endoscope in an automated washer, there is a recommendation that the endoscope can be stored in a drying cabinet for a period of 72 hours. The endoscope will then need to be sent off for a further cycle of decontamination.
- 3 If the endoscope is taken out of the drying cabinet and placed in a transportation tray for clinic, the recommendation is that it should be sent for a further decontamination

cycle after a period of 3 hour. However, there is no scientific evidence to support this time period: the latter being introduced as sensible practice in the days when clinics were perceived to last for 3 hours.

Rigid endoscopes

- 1 Autoclaving in a central sterilization unit is accepted as the decontamination model that minimizes the perceived risk of cross infection for rigid endoscopes
- 2 Rigid endoscopes are packaged after sterilization and will remain sterile until taken out of the packaging.

The consequences for hospitals

- 1 Hospitals will have to make serious decisions with regard to their preferred system for the decontamination of both rigid and flexible endoscopes. These decisions will require a balanced consideration of the various factors discussed above together with their analysis of the perceived risk.
- 2 To facilitate the central decontamination models, a large number of rigid and flexible endoscopes will need to be purchased or leased.
- 3 The infra-structure for central decontamination and sterilization must be present to facilitate this model. This will incur substantial capital funding for the necessary facilities to be developed.
- 4 Capital expenditure will be recurring and long-term as endoscopes require repair or replacement.

Andrew C. Swift
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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).

Further Reading

Article: Decontamination and traceability of flexible endoscopes

The Journal of Perioperative Practice 2007, 17: 257-264
Crawford A.

A prospective study of the efficacy of routine decontamination for gastrointestinal endoscopes and the risk factors for failure.

American Journal of Infection Control, 2006; 34: 0196-6553

Bisset L; Cossart YE; Selby W; West R; Catterson D; O'hara K; Vickery K

BSG Guidelines For Decontamination of Equipment for Gastrointestinal Endoscopy

BSG Working Party Report 2003. The Report of a Working Party of the British Society of Gastroenterology Endoscopy Committee

Disinfection, Sterilization and preservation

Spaulding EH, Chemical disinfection of medical and surgical materials, In: Block SS, ed. 4th edn. Philadelphia: Lea & Febiger, 1968.

Endoscope decontamination incidents in England 2003-2004.

Journal of Hospital Infection, 2007; 67: 0195-6701

Gamble HP; Duckworth GJ; Ridgway GL

Endoscopy-related infection: relic of the past?.

Current Opinion in Infectious Diseases, 2008; 21: 1535-3877

Seoane-Vazquez E; Rodriguez-Monguio R

Microbiologic assessment of disposable sterile endoscopic sheaths to replace high-level disinfection in reprocessing: A prospective clinical trial with nasopharygoscopes

Am J Infect Control 2009; 37: 408-413

Alvarado CJ, Anderson AG, Maki D

Review of Endoscope Decontamination

Practice in Scotland: November 2004 to May 2005

December 2005