

# **Guidelines for cleaning Fibreoptic Laryngoscopes**

## **Definitions**

### **Sterilization**

A process used to render the object free from viable micro-organisms including bacterial spores and viruses.

### **Disinfection**

A process, used to reduce the number of viable micro-organisms, which may not necessarily include bacterial spores and viruses. Disinfection may not achieve the same reduction in microbial contamination levels as sterilization.

### **Decontamination**

A combination of processes including washing, inspection and disinfection and/or sterilization used to render an instrument safe for handling and re-use.

## **Introduction**

These guidelines apply only to flexible fibreoptic laryngoscopes (also known as nasendoscopes and referred to later in this document as scopes):

- used for the examination of the nasal cavities, pharynx and larynx;
- which do not have suction or instrument channels.

Similar standards should apply to non-autoclavable rigid scopes, e.g. the ones used in a voice clinic. ENT departments are advised to purchase autoclavable rigid scopes wherever possible for future use.

Flexible nasendoscopes are delicate heat labile instruments, and thus not amenable to autoclave sterilization. High-level decontamination is usually adequate. Sterilization in normal circumstances is unnecessary as the endoscope does not usually penetrate mucosal barriers but may come into contact with blood through inadvertent trauma.

As there is little level one evidence published on the decontamination of flexible nasendoscopes in the ENT literature, much of the evidence and practice is extrapolated from the use of flexible endoscopes by our gastroenterology and pulmonary colleagues. However, in ENT practice, most endoscopes do not possess suction or biopsy channels or accessories: this is the significant difference from the endoscopes used in other procedures.

## **Aim**

The purpose of cleaning scopes is to prevent cross infection by transferring infective agents from one patient to another or between the patient and healthcare worker.

## **The risks of infection:**

### **a. Between the scope and the patient**

The incidence of transmission of infection by flexible fibrescopes is difficult to quantify as it is nearly impossible to prove that the scope was the definite causal factor. In gastroenterology procedures where flexible scopes are used the risk is reported at 1 in 1.8 million procedures. Potential sources of infected scopes include:

1. Failure of the decontamination process
2. Cracks in the scope or channels harbouring contaminated material
3. Contaminated water used for the final irrigation rinse
4. Poor storage and transport

Recently, concerns about prion diseases (particularly vCJD), which are resistant to all conventional methods of sterilization, have come to the forefront heightened by our relative lack of scientific knowledge. It is perceived that "the risk of transmission is probably extremely low provided that scrupulous attention to detail is routinely employed in the decontamination process after every patient." (British Society of Gastroenterology, 2003). Further to this, it has been highlighted that the role of cleaning process within a decontamination cycle plays a prominent part in the efficacy of the process.

### **b. Between the scope and healthcare worker**

Infection can be transferred by the user of the laryngoscope. Users should:

- decontaminate hands according to recommended methods between patients.
- the wearing of gloves is optional but recommended; hand wash after removing gloves.

## **Accountability**

Should an outbreak of infection occur, it is useful for contact tracing to refer to a separate log book kept with each instrument recording:

- patients' details;
- time & date of each use;
- names of the user and of the person responsible for decontamination;
- method of decontamination and the duration of immersion;

The logbook must be available and complete at all times (e.g. when on call out of hours).

Each scope should be individually identified so that the details of the instruments, including the serial number, are recorded in the patient's clinical notes.

## **Authorisation & Training**

Fibreoptic scopes are delicate instruments. Only those trained in their use and decontamination should be authorised to use or to decontaminate fibrescopes. ENT departments should set up a training programme with their Department of Infection Control, nursing staff and Allied Health Professionals (AHPs) for users and decontamination of fibreoptic laryngoscopes and maintain an up-to-date list of authorised personnel and what each individual authorisation covers. A named individual should be responsible for the programme. Occupational Health departments should be involved in the surveillance of healthcare workers.

## **Sites, personnel and modes of use**

Departments are recommended to consider what will be the best methods decontamination whilst caring for the continued efficient working of the fibreoptic scopes in:

- theatre;
- ENT & on other wards;
- outpatients & in outreach clinics;
- accident and emergency departments;
- at night and weekend emergencies;
- by locums;
- by AHPs e.g. Speech and Language Therapists performing endoscopic evaluations of voice and swallowing;
- private practice sites.

## **Storage and carriage of endoscopes**

If the used endoscope is to be transported from the place of use to the place of decontamination then it should be enclosed in a labelled disposable plastic bag. Even if the scope has only been loosely rinsed and dried, it should be placed in a protective bag before it is placed in the case.

## **Decontamination of fibreoptic laryngoscopes**

The environment in which flexible scopes are processed should be of a high standard, dedicated for purpose and away from treatment areas. At least two stainless steel sinks, double drained and separate hand-wash facilities are required.

Decontamination is a multi-stage process which includes high level disinfection and should be carried out between each patient. The scope

manufacturer must have approved the method used to uphold service contracts and warranties. Regular inspections are needed to check for leaks, cracks and surface irregularities which may hinder decontamination. The inspection should be visual and by formal leak testing which scope manufacturers recommend before each decontamination.

N.B. Scopes should be decontaminated at the end and beginning of each clinic or period of clinical use if the scope was last decontaminated three or more hours earlier.

### **Step One: Cleaning**

The most important initial factor in decontamination (particularly for prion disease avoidance) is cleaning which must remove all visible debris. The scope is manually cleaned and rinsed using running water and neutral low foaming enzymatic detergent by a trained member of staff as soon as the scope is removed from the patient. Over-vigorous cleaning may cause the flexible rubber at the end of the scope to ruck, creating crevices which may:

trap infective material;

be difficult to clean;

enlarge the bore of the scope making it more difficult and uncomfortable to pass.

### **Step Two: Chemical high level disinfection**

Owing to unacceptable risks to staff exposed it is no longer possible to use glutaraldehyde. Suitable liquids now include electrolysed saline (e.g. Sterilox), chlorine dioxide (e.g. Tristel), peracetic acid (e.g. Steris, Nu-Cidex, Perasafe, Gigasept, Dopsidex). Do not use disinfectant impregnated wipes as sole means of decontamination. This process cannot be validated reliably and further work is needed to confirm efficacy in this setting.

The ideal disinfecting agent and process:

- a. is effective: kills bacteria, viruses, spores, fungi and denatures or removes prions
- b. is stable, re-usable, lasts long time without need to replenish
- c. is not a health hazard to patient, health care worker or environment
- d. is quick, therefore ensuring rapid turnover for scope use, and also limiting the number of scopes needed
- e. has little collateral costs e.g. staff, environment, equipment
- f. does not damage the scope
- g. is validatable, amenable to quality control
- h. is accessible 24hrs of the day
- i. has low capital and maintenance costs.

There is no ideal disinfecting agent!

COSHH profiles on all agents in use must be available and up to date.

## **ELECTROLYSED SALINE**

The advantages of electrolysed saline are that:

- The effective material is bleach and once completed any substance on the scope is salt water and no further washing is needed;
- Mechanical cleaning is included as part of the process.

The disadvantages of electrolysed saline are that:

- the scope must be taken from its site of use to a suitable machine;
- scopes must be coated with an adequate approved protective layer before they are submitted to the process;
- installing an electrolysed saline system involves a significant capital cost.

## **PERACETIC ACID**

Peracetic acid has a slightly pungent smell of vinegar but is safe for everyday use. It may be used in a totally mechanised process.

The advantage is that:

- coating is not needed

The disadvantage is that:

- the peracetic acid must be rinsed off the scope with a suitable agent (sterile Water for Irrigation BP) which adds to the costs.

It may also be used locally with additional advantages and disadvantages.

The advantages are that:

- little capital or running costs are involved (the purchase of the chemical; suitable mixing methods and a stand to immerse the laryngoscope in peracetic acid);
- disinfection can be performed quickly and safely close to the point of use by immersion in peracetic acid for ten minutes so fewer laryngoscopes are needed.

The disadvantage is that:

- a suitable exhaust-ventilated room is needed locally for decontamination since it can cause skin reactions, and has the potential for upper respiratory tract irritation (see COSHH profile).

## **CHLORINE DIOXIDE**

This is a broad spectrum agent with rapid activity against vegetative bacteria including mycobacteria, viruses and spores. Chlorine dioxide is potentially corrosive, and some solutions are marketed with a corrosion inhibitor. Users of some manufacturers' endoscopes are advised to perform daily pre-use inspections as a condition for service contracts and warranties to remain in effect. Advantages and disadvantages are much as for peracetic acid.

Any of the above methods are acceptable ways of decontaminating fiberoptic scopes between uses. Each chemical must be used in accordance with the

manufacturer's guidelines and for the time specified. Check with the manufacturer of the scope that the chemical and scope are compatible and enquire about any measures needed to protect the scope.

The member of staff responsible for sterilization must complete the sterilization documentation and should certify the expiry date of the batch used, the date the solution was made up, the date it will be discarded and the times of immersion and removal of the individual scope.

### **Step Three: Rinsing and drying the fiberoptic scope**

Irritant decontaminating agents must be washed from the fiberoptic scope before use. Dry with an alcohol swab.

### **Step Four: Transport and storage of the fiberoptic scope.**

Cleaned scopes should be transported and stored in marked clean sealed bags which have been appropriately labelled. The routine use of the scope case alone for transport is not acceptable. The scope and sealed bag may be placed in a rigid case for additional protection. Once used the scope should be placed in a bag labelled "contaminated".

### **Disposable sheaths as an alternative to disinfection.**

Sheaths are available to cover fibrescopes and prevent contamination. Some feel that the view with a sheath is not as good as without, although one paper suggests that there is no difference (Winter et al, 2002). Also the sheath only partially covers the scope.

There are reports of damage to fibrescopes from the unskilled removal of endosheaths. Staff using such sheaths for fiberoptic laryngoscopy must be trained in their use and safe removal.

After removing the sheath carefully it should be checked for failure by:

- inspecting the sheath for tears;
- inspecting the scope for moisture;
- by inflating the sheath gently e.g. with a bladder syringe (The bladder syringe may be used several times);

If there is any sign of failure the sheath should be fully decontaminated.

Sheaths allow a rapid turnover but have a significant cost.

Scopes must still go through a complete decontamination cycle before use if they have not been decontaminated within the last three hours, and must go through a complete cycle at the end of every session of use.

## **Automated mechanical cleaning methods**

Cleaning may be performed by a variety of automated machines. The manufacturers' instructions for use must be followed.

The advantages are that:

- it can be properly validated;
- damage from over-vigorous manual cleaning cannot occur;
- it is a controllable process and specific parameters can be set;
- it minimises risk to staff for manual processing.

The disadvantages are that:

- it incurs significant capital costs;
- it requires the scope to be returned to a suitable machine;
- at present it has long turnaround times for each scope;
- the machine may be located away from ENT department.

## **Audit**

As cross infection is likely to be rare and difficult to confirm in individual cases, audit should be performed by the Departments of Otolaryngology Head and Neck Surgery and Infection Control in individual trusts by random check of instruments at all sites of use in addition to the regular routine monitoring mentioned above. This audit should include all outpatient instruments which come in contact with patients and of staff techniques of handwashing. Such an audit of scope decontamination should be performed at least annually.

## **Future Research**

There is little firm evidence regarding the hazards of transmitted infection with fiberoptic laryngoscopes without channels. The potential risks and the costs of decontamination, damage to delicate and expensive instruments by inexpert techniques of re-processing and the purchase and subsequent replacement and updating of extra instrument need to be investigated. Consideration should be given to the logistic challenges and potential associated costs if decontamination is performed at a distance from the site of use.

The development of smaller "bench top" machines suitable for the decontamination of all scopes without channels, close to the point of use, would be a significant improvement on the present methods of decontamination. Manufacturers are being encouraged to develop these smaller "bench top" machines.

The Tristel wipe system potentially offers a relatively simple and easy method for decontaminating ENT flexible scopes, however at the time of going to press this system has not received approval from the MRHA and negotiations are continue.

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