

BSG Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy



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

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Summary

1. Decontamination of endoscopes should be undertaken by trained staff in dedicated rooms. Staff training programmes should be implemented and documented. Training should include an awareness of the channel configuration of all endoscopes and of the automated endoscope reprocessors (AER) and available irrigation adaptors.
2. Traditionally it has been recommended that, before the start of each list, each endoscope to be used should undergo a full reprocessing cycle unless last used and decontaminated within the preceding 3 hours. Many units are now using purpose built drying and storage chambers, some of which have been shown to prevent colonisation of endoscope channels for up to 72hr (some manufacturers claim 7 days). Where appropriate quality assurance data is available, the use of such chambers may obviate the need for repeat endoscope reprocessing at the start of each list.
3. Thorough manual cleaning with a compatible enzymatic detergent, including the brushing and flushing of all accessible endoscope channels, must be undertaken before automatic endoscope disinfection. This routine must be undertaken during lists, between patients and after each patient examination.
4. Units should move away from using aldehyde- and alcohol-based disinfectants because of their fixative properties, which in theory could anchor prion and other protein within endoscope channels.
5. Single use disinfectants are now widely used within AER. Units in hospitals serving large populations of patients at risk of variant CJD (such as haemophilia centres) should employ either single use disinfectants or purpose-designed automated reprocessors that generate single use biocides.
6. All disinfectants should be used at the correct temperature and concentration in accordance with the manufacturers' instructions. Some manufacturers recommend the use of test kits or strips in order to ensure the optimal activity of their product. Machine testing should include the accuracy of the dosing system.
7. It is important to ensure that the endoscope manufacturer has approved the chosen disinfectant as being compatible for use in decontaminating their product, and that the disinfectant is also compatible with the AER in which it is being used.
8. It is essential that all reprocessing stages are included after every use of the endoscope, and that none are omitted. It is also essential that all channels of all endoscopes are reprocessed after every use of the endoscope, even if the channels were not used during the preceding patient procedure.
9. Automated endoscope reprocessing machines (AER) should be used for all endoscope decontamination following manual cleaning. Manual disinfection is unacceptable. Users must ensure that the correct adaptors are available for all endoscopes to ensure irrigation of all channels.
10. Filtered air should be used as part of the drying process at the end of the working day prior to endoscope storage. An alternative is to dry and store endoscopes in cabinets that are designed to deliver high efficiency particulate filtered air to the internal channels at the appropriate temperature and flow rate. Because of its fixative properties the use of isopropyl alcohol is no longer recommended.
11. Water used in AER should be free of particulate contamination and of micro-organisms. This can be achieved either by using bacteria-retaining filters or by other methods, for example reverse osmosis. In-line water softeners may be

needed if the local supply delivers hard water. The final rinse water should be sampled from the AER and regularly tested for its microbiological quality in accordance with the current relevant Health Technical Memorandum (HTM).

12. A record should be kept of the serial number of each endoscope used in each patient. This log should include any loan endoscopes. This is important for any future contact tracing when possible endoscopic transmission of disease is being investigated. Details of the AER and cycle parameters used in decontaminating that endoscope should also be kept.
13. The agent of variant Creutzfeldt-Jakob disease (vCJD) is resistant to all forms of conventional sterilisation. The risk of transmission of this agent is probably extremely low provided that scrupulous attention to detail is routinely employed in the decontamination process after every patient. In particular all accessible endoscope channels should be brushed through with a single use purpose-made device or brush tipped wire assembly that has an appropriate length and diameter for each channel.
14. A group of people "at risk" of harbouring vCJD has been defined. Any endoscopic procedure that breaches gut mucosa and is followed by the withdrawal of an unsheathed accessory through the working channel of an endoscope is deemed "invasive". Procedures that cause tissue vaporisation (e.g. diathermy) are also deemed "invasive". The performance of an "invasive" procedure in an "at risk" patient will necessitate the subsequent quarantining of the endoscope used.
15. The performance of an "invasive" procedure (defined in 14 above) in a patient with suspected or confirmed vCJD will again necessitate quarantining the endoscope. A separate paper (referenced herein) gives practical advice to the endoscopist on ways of undertaking some forms of therapeutic endoscopy (e.g. PEG) without contaminating the working channel of the endoscope.
16. 'Single use' accessories should always be used in preference to reusable accessories. The choice of single use biopsy forceps, guidewires and cytology brushes helps to minimise any possible risk of transmitting prion disease. Reusable accessories should only be used in situations where no single use equivalent accessory exists, and procedures should be available for tracking each patient use in these circumstances.
17. Rubber biopsy port caps must be discarded after all procedures involving the passage of biopsy forceps, guidewires and/or other accessories through the endoscope. Other detachable valves (primarily air/water and suction valves/pistons) should be manually cleaned according to manufacturers' instructions, then decontaminated with their corresponding endoscopes in an AER, keeping the valves and endoscopes together as a traceable unique set.
18. Health surveillance for staff should be considered, in consultation with occupational health departments for exposures to disinfectants that are not aldehydes or chlorine-releasing agents or other strong irritants. If agents similar to glutaraldehyde are used, then health surveillance should be carried out. Occupational health records should be retained for 40 years.
19. Those involved in endoscopic practice should be immunised in accordance with local occupational health and infection control policies. All staff should wear single use gloves that are changed after each procedure. Staff involved in endoscope decontamination should also wear appropriate protective clothing.
20. Out of hours endoscopy should not be done unless there is an endoscopy assistant available who has been trained in decontamination practice.
21. A summary of recommendations is given at the end of the document. Most are based on advice from expert opinion, which includes advice from the Medicine and Healthcare Products Regulatory Agency (MHRA) (formerly the Medical Devices Agency) and from other Working Parties. Some of the recommendations are derived from microbiological studies. Controlled trials in the field of endoscope decontamination are lacking because of a reluctance to expose "placebo control" patients to an infection risk.

22. A summary guideline on avoiding pitfalls in endoscope decontamination practice has been produced by the MHRA in response to an incident that occurred in 2004. This is set out in Box 3 at the end of this document.

1. Introduction

Flexible endoscopes are complex reusable instruments that require unique consideration with respect to decontamination. In addition to the external surface of endoscopes, their internal channels for air, water, aspiration and accessories are exposed to body fluids and other contaminants. In contrast to rigid endoscopes and most reusable accessories, flexible endoscopes are heat labile and cannot be autoclaved.

The BSG first published recommendations on endoscope decontamination practice in 1988, and the recommendations from the fourth working party appeared in Gut in 1998 (1). In 2002 a fifth working party reconsidered the recommendations for decontamination of endoscopes and their devices, prompted by the following developments:

- a. A Health and Safety Executive report that safer alternatives to glutaraldehyde should be used within health care settings.
- b. Emergence of variant Creutzfeld Jakob Disease (vCJD) as an important pathogen in man.
- c. Publication of an updated Medical Devices Agency (MDA) Device Bulletin DB2002 (05) on decontamination of endoscopes. (2)

In 2004 a review of endoscope decontamination practice was undertaken in Northern Ireland in response to an incident where stained fluid was seen to emerge from an auxiliary endoscope channel, the existence of which was not known to staff. This report recommended that the updated BSG Guidelines should give special emphasis and advice on the decontamination of elevator wire and auxiliary water channels (3).

The Health Act was published in 2006. This 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 competencies for their role. It decrees the need for monitoring systems to ensure that decontamination processes are fit for purpose and meet required standards. Finally it requires that there are systems in place for tracking reusable medical devices (such as endoscopes and reusable accessories) through decontamination processes, not only to assist with assuring their quality, but also to enable the identification of patients on whom the medical devices have been used.

The 6th Working Party met in October 2006 to consider new developments and recommendations, including (a) the optimal modes for decontaminating water bottles and endoscope valves (pistons); (b) the latest recommendations for reducing the risks of endoscopic transmission of vCJD, including the tracking of equipment; and (c) updated recommendations on drying and storage of endoscopes, given the evolving range of purpose-built chambers designed for this purpose.

2. Transmission of Infection at Endoscopy

A guiding principle for decontamination is that of universal precautions: any patient must be considered a potential infection risk, and each endoscope and device must be reprocessed with the same rigour following every endoscopic procedure. Few data exist as to the absolute risk of transmission of infection from patient to patient at endoscopy. In 1993 one report suggested that the reported frequency was 1 in 1.8 million procedures (4). Estimating the infection risk is difficult for several reasons: complications such as septicaemia following ERCP may be due to the induction of endogenous infection as opposed to the endoscope being a vehicle of infection. Additionally the onset of infections complicating endoscopy may be delayed until after the patient has been discharged home following their procedure. There is also the potential for transmission of infective particles with very long incubation periods (vCJD, for example).

Endoscopy-induced infection is usually due to procedural errors in decontamination (5,6). These include failure to decontaminate all channels including auxiliary and duodenoscope elevator wire channels, and the use of incompatible connectors between endoscopes and AER (3). Other potential risk factors for transmission of infection at endoscopy include the use of older endoscopes with associated surface and working channel irregularities, and the use of contaminated water bottles or irrigating solutions. Further potential vehicles of infection are inadequately designed or improperly maintained AER, the use of substandard disinfectant, or inadequate drying and/or storage of endoscopes.

There have been concerns regarding the transmission of hepatitis C virus (HCV) following an instance reported in 1997 (7). Transmission of viral infection occurred because of (a) failure to brush the biopsy channel, (b) failure to clean ultrasonically and steam sterilise reusable biopsy forceps, (c) inadequate exposure to the liquid chemical germicide. Adherence to current reprocessing guidelines effectively eliminates the risk of HCV transmission from endoscopy (8, 9). In fact the hepatitis viruses are among the micro-organisms most sensitive to disinfectants in current use.

Glutaraldehyde-based products have historically been the most commonly used disinfectants in endoscopy units worldwide. Most reports of transmission of bacteria such as pathogenic *E. coli*, *Salmonella*, *Pseudomonas*, *Enterobacter* and *Serratia* spp. predate not only the introduction of glutaraldehyde for disinfection but also the practice of using fully immersible endoscopes and exposing all working channels to the decontamination process (5).

Three types of micro-organisms have merited particular attention in recent years.

- a. Mycobacteria: the emergence of multi-drug resistant strains of *Mycobacterium tuberculosis* and the high incidence of infections with *M. avium intracellulare* among HIV infected patients has led to a greater awareness of the risk of transmission of Mycobacteria during bronchoscopy. Mycobacteria in general, and especially waterborne mycobacteria (such as *M. chelonae*) are extremely resistant to glutaraldehyde.
- b. Bacterial spores (*Bacillus* and *Clostridium*) – spores from these organisms can be isolated from endoscopes but there are no reported cases of transmission of these infections by endoscopy. Studies have shown that *Clostridium Difficile* spores can be completely inactivated by a standard decontamination procedure (10).
- c. Pathological Prions including Creutzfeldt Jakob Disease and vCJD. These infectious particles are extremely resistant to standard decontamination procedures. Recommendations for minimising the risk of transmission of prion proteins are discussed in detail later in these guidelines.

Although the greatest potential risk is transmission of infection from one patient to another using the same contaminated endoscope, there is also the potential for transmission of infection from patients to healthcare workers. Studies have suggested that endoscopes are potential vectors for the transmission of *Helicobacter pylori* (11). Another example is the acquisition of *Herpes simplex* ophthalmitis following oesophageal biopsy (12). Healthcare workers are also at potential risk of infection with blood-borne viruses transmitted via sharps, such as spiked biopsy forceps. (See Section 7: *Protecting the Operator*)

Traditionally patients harbouring potentially infectious micro-organisms are scheduled for the end of endoscopy lists in order to minimise cross-infection. Given the universal endoscope decontamination regime, which presumes that all patients are potentially infectious, there is not normally a need to examine patients with known infection last on the list. Nonetheless prevailing infection control policies should be adhered to, and these often include scheduling patients with meticillin-resistant *Staphylococcus aureus* (MRSA) at the end of lists.

3. Decontamination of endoscopes – general considerations.

Sterilisation is defined as the complete destruction of all micro-organisms including bacterial spores. Sterilisation is required for devices that are normally used in sterile areas of the body (e.g. laparoscopes, microsurgical instruments). Flexible endoscopes (which make contact with mucous membranes but do not ordinarily penetrate normally sterile areas of the body) are generally reprocessed by high level disinfection rather than sterilisation in order to kill bacteria, viruses, mycobacteria and some spores. Most flexible gastrointestinal endoscopes would not withstand the conditions normally used in a sterilisation process.

Endoscopes are routinely exposed to mucus and other gastrointestinal secretions, blood, saliva, faeces, bile, and sometimes pus. The process of decontamination comprises two basic components:

- a. manual cleaning, which includes brushing with a purpose-built single-use cleaning device, and exposure of all external and accessible internal components to a low-foaming enzymatic detergent known to be compatible with the endoscope;
- b. automated disinfection, rinsing and drying of all exposed surfaces of the endoscope.

It is essential that all reprocessing stages are included after every use of the endoscope, and that none are omitted. It is also essential that all channels of all endoscopes are reprocessed after every use of the endoscope, even if the channels were not used during the preceding patient procedure. Failure to follow these recommendations may not only lead to transmission of infection, but also to misdiagnosis (e.g. if pathological material from one patient is included in specimens from the next patient) and to instrument malfunction and shortened lifespan.

Decontamination should begin as soon as the endoscope has been removed from the patient. Before the endoscope is detached from the light source/videoprocessor a *preliminary cleaning* routine should be undertaken. Water and detergent should be sucked through the working channel in order to clear gross debris and ensure that the working channel is not blocked. Similarly the air and water channels should be irrigated with sterile water, not only to check for blockages but also to expel any blood, mucus and other debris. The insertion shaft is wiped down externally and checked for any bite marks or other surface irregularities. The endoscope is then detached from the light source/videoprocessor, removed to the reprocessing room and attached to a leakage tester to check the integrity of all channels before reprocessing.

When transporting endoscopes to and from areas outside the endoscopy unit, they must be transferred in covered rigid receptacles, not only to avoid damage to the endoscope, but also to protect staff and the public. The receptacle will itself need to undergo a separate decontamination process.

The second stage is the *dismantling* of detachable parts of the endoscope, which includes the removal of valves and water bottle inlets. Some endoscopes have detachable tips which should also be disengaged from the insertion tube at this stage. Biopsy port caps should be discarded whenever breached by biopsy forceps or any other accessory passed down the working channel during the preceding endoscopy procedure. Detachable parts that are to be re-used (e.g. air/water and suction valves/pistons) should be reprocessed together with the corresponding endoscope as a unique set in order to allow traceability (2). The practice of ultrasonic cleaning of valves in batches should be abandoned.

The third stage is *manual cleaning* and rinsing of all exposed internal and external surfaces. A low-foaming enzymatic detergent that has been specifically designated for medical instrument cleaning should be used at the appropriate dilution according to the manufacturer's instructions. Whilst enzymatic detergents have not been conclusively shown to be superior to other detergents in endoscope decontamination, they have the ability to digest mucus and other biological material provided that sufficient contact time is given. These properties are potentially very important in the manual cleaning of narrow endoscope channel lumens. All accessible channels should be exposed to detergent by means of

brushing with a purpose-built single-use cleaning device. This is followed by the rinsing of all external surfaces and internal channels in a separate sink filled with clean water.

Detachable components (e.g. air-water and suction valves/pistons), once removed from the endoscope, should be manually cleaned by washing and brushing their external and internal surfaces in detergent, then rinsing them in water prior to reprocessing.

Some endoscopes (particularly older models) have channels that are not accessible to automated decontamination procedures. Special consideration must be given to the cleaning of auxiliary water channels, exposed elevator wire channels and balloon inflation channels in endoscopic ultrasound probes. The channels of these models must be manually cleaned and disinfected according to manufacturers' instructions.

The fourth stage is *high level disinfection* using a liquid chemical germicide within an AER. Manual disinfection is unacceptable and must not be done. The endoscope is reprocessed having had its detachable components (e.g. air-water and suction valves/pistons) removed from it; the separated components are appropriately collected or connected within the automatic endoscope reprocessing machine, and reprocessed simultaneously with the endoscope. It is important to note that even the most modern and sophisticated AER do not replace the need for prior thorough manual cleaning including brushing of all working channels. The process of decontamination should be concluded with *further rinsing* with sterile or filtered water, followed by *proper drying* of each endoscope.

Throughout each decontamination cycle, tracking of the personnel and patient association of each endoscope is undertaken using manual or electronic methods. For this to happen each endoscope must have a unique identification code or bar code. Each step of the decontamination cycle should be recorded, including the identity of the person undertaking each step, and this information should be linked to each individual patient examined with that endoscope. The detachable components should be kept with their corresponding endoscope, forming a unique set. A record of the decontamination process should be retained. The tracking system operating in each unit should be subject to regular appraisal. There must also be a means of tracking each patient use of reusable endoscopy accessories.

The decontamination of endoscopy equipment is a specialised procedure and should only be carried out by personnel who have been trained for the purpose and who have an understanding of the principles involved. It should be done in a dedicated area with atmospheric extraction facilities that have been maintained according to manufacturers' instructions. The safe working practices in the decontamination area of each unit should be clearly documented and understood by all staff. Comprehensive records of all decontamination processes and all staff training must be maintained. If an emergency endoscopic procedure is done out of hours, someone with knowledge of the endoscope decontamination process must be available to prepare and clean the equipment.

Water bottles provided with the latest generation of endoscopes are autoclavable, and should be changed and filled with sterile water after each endoscopy session. They should be detached, emptied and cleaned as per manufacturers' instructions, and then sent for sterilisation. Water bottles do not need to be tracked for purposes of traceability.

Service contracts and guarantees may not be honoured if incompatible disinfectants and detergents have been employed. The MDA Device Bulletin (2) lists the information to be supplied by manufacturers of endoscopes, accessories and disinfectants.

The Health and Safety at Work Act 1974 requires employers to ensure, as far as is reasonably practicable, the health, safety and welfare of all employees. The Act also requires employees to comply with the precautions established to ensure safe working. The Control of Substances Hazardous to Health Regulations 1994 (COSHH) requires employers to assess the risk to the health of staff by exposure to hazardous chemicals such as glutaraldehyde and its derivatives, to minimise and to avoid such exposure where this is reasonably practicable, and otherwise to

ensure adequate control. Engineering methods of control must be used in preference to personal protective equipment.

4. **Special considerations: CJD and other prions**

Creutzfeldt-Jakob disease (CJD) is a member of a group of neurological disorders known as the transmissible spongiform encephalopathies (TSEs) or prion diseases, which affect both animals (scrapie in sheep, BSE in cows) and man. The precise nature of the transmissible agents responsible for these disorders is unknown, but there is widespread acceptance of the prion hypothesis, which states that the agent is composed of an abnormally folded form of a host-encoded protein, prion protein. The normal prion protein (PrP^C) is expressed in many tissues, but occurs at highest levels in neurones in the central nervous system (CNS). The abnormal form of the protein (PrP^{Sc}) accumulates in the CNS in prion diseases and, as the presumed infectious agent, it is remarkably resistant to most forms of degradation.

The sporadic form of CJD affects approximately 1 person per million per annum worldwide. Variant CJD (vCJD) is an acquired form of CJD affecting mainly young adults. It was first reported in 1996, and it exhibits a unique neuropathological phenotype (13). It is now accepted that bovine prions passed into the human population through the consumption of BSE-infected bovine tissues and that the transmissible agent responsible for vCJD is identical to the BSE agent (but different from the agent in sporadic CJD). The incubation period for vCJD could be as long as 30 years. Invasive procedures (such as endoscopy with biopsy) have the potential to transmit the disease from affected individuals in the incubation phase.

The distribution of the PrP^{Sc} in the body is different in sporadic and vCJD, reflecting their different pathogenesis. In the case of sporadic CJD, prion infectivity is largely limited to the CNS and retina. Gastrointestinal endoscopy is unlikely to be a vector for the transmission of sporadic CJD because infected tissue is not breached during the procedure. No special precautions are necessary during or after the procedure and the endoscope should be cleaned and disinfected in the normal thorough way. By contrast, in vCJD the lymphoreticular system throughout the body contains PrP^{Sc} at the time of death, and may contain significant levels of infectivity during the incubation period (14). Since lymphoid follicles and germinal centres are widely distributed in the gastrointestinal tract (and are often biopsied), endoscopic examination of patients who are incubating vCJD could expose the instrument (and particularly the biopsy forceps) to PrP^{Sc}.

In general the risks of transmitting vCJD from one person to another are dependent on the infectivity of tissues involved, the amount of tissue contaminating the instrument, the effectiveness of decontamination processes and the susceptibility of subsequently exposed patients. Experimental studies suggest that levels of infectivity in prion diseases are highest in the CNS and retina, which are around 100-fold higher than in the tonsils and other lymphoreticular tissue. The abnormal form of the prion protein can be detected in rectal tissue (15,16). The risk of transmitting vCJD through an endoscopy is likely to be minimal, but contamination of the endoscope and forceps as a result of biopsying lymphoid tissues may represent a larger (but currently unquantifiable) risk. The greatest potential risk ensues from biopsying the terminal ileum because the abundant Peyer's patches in this region may contain significant levels of prion protein in those incubating vCJD (15). The biopsy forceps and the colonoscope become potential vectors for disease transmission under these circumstances.

It should be emphasised that aldehyde disinfectants, such as ortho-phthalaldehyde (OPA) and glutaraldehyde, fix protein, a property which may not only anchor prion protein within endoscope channels, but also render it more difficult to remove by other means. Hence the use of these agents should be avoided when decontaminating endoscopes that have been used in patients with definite or suspected vCJD, or in patients considered to be at risk of vCJD for public health purposes.

At present conventional sterilisation methods cannot reliably destroy the infecting agent in vCJD. All those involved in endoscopy must recognise the potential for transmission through poor decontamination practice, and ensure that procedures are in place to minimise contamination and maximise cleaning. Best practice

defined in these terms (17-19) will reduce a very small, potential risk to one too small to be measured.

Disinfection must always be preceded by thorough manual cleaning, with all accessory and other accessible channels brushed and washed with enzymatic detergent and rinsed with water. It follows that brushes or other purpose built catheters used to clean the channels of the endoscope should also be single-use, both to ensure maximum efficiency of cleaning and to reduce the risk of inoculating other endoscopes. Existing detergents are ineffective against prion proteins, but specialised enzymatic detergents are at an advanced stage of development. Meticulous manual cleaning of the endoscope is probably the best way to protect against person-to-person transmission.

Biopsy port caps should be discarded after any endoscopic procedure involving use of any accessory passed through the valve. Every effort should be made to employ single-use equipment, and in some circumstances this may be a cheaper as well as safer option. Adequate funding must be available to endoscopy units for the purchase of single-use biopsy forceps, cytology brushes, guidewires and other accessories. In addition 'random' biopsies, particularly of the terminal ileum, should be kept to a minimum as lymphoid tissue is distributed widely throughout the gastrointestinal tract.

It is possible to obtain special endoscopes for patients known to have vCJD who require an endoscopy. Such dedicated endoscopes are available from the National CJD Surveillance Unit in Edinburgh and some other regional centres.

Clearly patients incubating vCJD may undergo endoscopy and be a potential unrecognised infective source for others. Even though the risk of transmitting infection by endoscopy is very small, all units should have a process for tracking equipment used during each procedure in the event that a patient is subsequently suspected of having, or being at high risk for, the disease. Serial numbers of all endoscopes and accessories must be recorded for each patient examined, and endoscopes must be properly tracked through their decontamination processes.

A working group of the British Society of Gastroenterology met in 2005 to produce a consensus document with the Department of Health TSE Working Group entitled "At risk of vCJD for public health purposes". This has recently been updated, together with Annex F of the UK Department of Health TSE guidance. These web-based documents stratify the potential risk of endoscope contamination according to the patient vCJD risk, the procedure performed and the methods employed (20). They also give practical advice to the endoscopist on ways of avoiding such potential contamination during procedures such as endoscopic dilatation or percutaneous endoscopic gastrostomy (for the latter, there are also the alternatives of radiological or surgical gastrostomy).

Individuals at risk of vCJD include people (e.g. those with haemophilia) who received plasma based concentrates between 1980 and 2001, and also a group who received blood or plasma products derived from donors who subsequently developed vCJD. The "at risk" group also includes patients with primary immunodeficiency syndromes, Guillain Barré syndrome and other recipients of transfusions derived from multiple donors (e.g. >80 units of blood).

Endoscopic procedures with the potential to introduce vCJD-contaminated tissue particles into the working channels of endoscopes are deemed potentially **invasive procedures** when mucosa is breached or vaporised and the endoscope accessory and/or tissue vapour make contact with the working channel of the endoscope. Invasive procedures include mucosal biopsy, sphincterotomy, and any procedure employing diathermy or other forms of tissue vaporisation. If such an invasive procedure is done during endoscopy of an "at risk" patient it becomes necessary to quarantine the endoscope. Unless the potential vCJD infection risk to that endoscope can later be rescinded, the quarantined endoscope cannot return to normal use, and will only be available for use with the same patient in future or, alternatively, for a patient with established vCJD. At the time of writing, endoscope manufacturers are expected to be able to offer refurbishment of potentially infected endoscopes, funded centrally from UK Health Departments, allowing some quarantined endoscopes to be returned to use. Prototypes of sheathed biopsy forceps are also under evaluation.

If invasive endoscopy has been performed in a patient with or at risk of vCJD (or such a patient retrospectively discovered to have undergone invasive endoscopy) the endoscope used should be quarantined while advice is obtained from the CJD Incidents Panel (tel: 020 8327 6074 or see CJD webpage of www.hpa.org.uk). If a contamination risk is confirmed, it should remain quarantined pending possible refurbishment, or retained for dedicated re-use for the same patient.

It is recommended that single use disinfectants should be used for endoscopes that have been used in "at risk" patients, and that such endoscopes should be decontaminated separately from any other endoscope prior to quarantining. The dilutions and flows of fluids preclude any significant risk of contaminating the AER itself.

Rigid metal sigmoidoscopes and proctoscopes should be thoroughly cleaned and then autoclaved (15). The same recommendations apply for all other surgical instruments with the capacity to withstand this method. This should not be interpreted as being a procedure that eliminates risk altogether given the resistant nature of prion protein. There is no substitute for thorough manual cleaning.

As research progresses, it is likely that other procedures will be developed to inactivate prion infectivity and to remove proteins from instrument surfaces. The development of such techniques (along with more sensitive tests for prion detection) may well have an impact on future advice concerning endoscopy and transmissible spongiform encephalopathies.

*Regularly updated healthcare guidelines appear in the transmissible spongiform encephalopathy section of the Department of Health website:
<http://www.advisorybodies.doh.gov.uk/acdp/tseguidance/Index.htm>*

5. Disinfectants

The ideal disinfectant would be:

- Effective against a wide range of organisms including blood-borne viruses and prion proteins.
- Compatible with endoscopes, accessories and AER.
- Non-irritant and safe for users.
- Environmentally friendly for disposal.

Other factors that will influence the choice of disinfectant include the process of dilution, stability of the solution and the cost of using the particular disinfectant (e.g. costs of the appropriate AER, storage space, and conditions required for use, including staff protection measures). It is essential to use disinfectants in accordance with their manufacturers' instructions. Attention must also be paid to directions from manufacturers of AER and endoscope manufacturers. Some endoscope manufacturers advise users to undertake specified inspection routines as a precondition of honouring their service contracts and warranties.

The material safety data sheet (MSDS) must be obtained for all products to ensure appropriate safety precautions, if applicable, are followed.

Although less irritant than glutaraldehyde, all the disinfectants discussed below may under certain conditions become potential skin and respiratory irritants in some users. This risk can be circumvented if the agents are used within the confines of AER in well ventilated rooms. Health care workers should employ personal protective equipment while handling these disinfectants during endoscope decontamination. (Section 7). A spillage procedure and kit must be available within the department.

The widely used disinfectants were reviewed in detail elsewhere (19) and are briefly discussed below. Their properties are shown in Table 1.

a. Aldehyde-based disinfectants

A formerly widely-used glutaraldehyde-based disinfectant (Cidex ®) has been withdrawn from the United Kingdom market by its manufacturer. This is not only because there have been advances in the development of disinfectants with superior bactericidal activity, but also because glutaraldehyde is chemically related to formaldehyde, and has similar toxic effects on skin and mucous membranes. Resulting adverse effects include

severe dermatitis, conjunctivitis, sinusitis, asthma, and even chemical colitis. A further problem with glutaraldehyde-based disinfectants is their potential to cross-link residual protein material. The resulting amalgam is very difficult to remove from working channels of endoscopes that have been repeatedly flushed with aldehydes. This again underscores the importance of manual pre-cleaning and brushing of all accessible internal channels and valve chambers before disinfection.

Glutaraldehyde and its derivatives kill most bacteria and viruses (including human immunodeficiency virus and hepatitis B) in less than five minutes. Mycobacteria are more resistant to 2% glutaraldehyde, and earlier guidelines recommend that endoscopes are immersed for 20 minutes in 2% glutaraldehyde at room temperature (1).

Ortho-phthalaldehyde (OPA, 0.55% solution) is more stable and has a lower vapour pressure than glutaraldehyde. It is therefore practically odourless and does not emit noxious fumes. It is non-flammable and is stable at a wide pH range. It has better bactericidal and mycobactericidal activity than 2% glutaraldehyde (22-24). In use testing of OPA on endoscopes has shown cidal activity achieving a reduction of greater than five logs. and stability over a two-week period (25). The manufacturers of Cidex OPA® recommend the daily use of OPA test strips to monitor the activity of reused batches of disinfectant solution. OPA, like other aldehydes, can stain and cross-link protein material. It can therefore not be recommended for the decontamination of endoscopes after use in patients with risk factors for vCJD.

Other aldehyde derivatives and combinations are available. Users should ensure the required spectrum of antimicrobial activity is present and that they follow the manufacturers recommendations for use.

b. Peracetic Acid

Numerous peracetic acid based disinfectants are on the market. They have been shown to be rapidly effective against a wide range of micro-organisms (25-30). However, speed of activity can vary and appears to be related to the pH and concentration of the solution. Users should ensure they adhere to the manufacturers' instructions in terms of contact times and use life. Agents are available as reusable or single use. The reusable products often have test strips for establishing the minimum effective concentration. Compatibility also appears to vary and users should take advice from the endoscope manufacturers.

c. Electrolysed acid water

This is a mixture of active elements derived from salt by electrolysis through a proprietary electrochemical cell. It is important that the parameters for electrolysis e.g. pH, Oxidation-reduction potential etc. are strictly adhered to, as it is only under these conditions that a biocide is produced. The "Sterilox®" system automatically changes and regenerates the active biocide, hypochlorous acid, every 23hr within an enclosed chamber.

Electrolysed acid water is rapidly effective (31-33) but again activity and compatibility with endoscopes can vary according the parameters of the solution. Furthermore its efficacy is reduced in the presence of organic matter, which further underscores the need for assiduous manual cleaning before automatic reprocessing.

d. Chlorine Dioxide

Chlorine dioxide is a broad spectrum agent with rapid activity against vegetative bacteria including mycobacteria, viruses and spores (34,35). Solutions are available as reusable or single use. Test kits are available to determine the concentration

e. Alcohols

Due to its fixative properties the use of isopropyl alcohol in the process of drying endoscope channels at the end of the day is no longer

recommended. Heated air or commercially available drying/storage cabinets should be employed instead.

- f. Sterilisation processes
Ethylene oxide, low temperature steam and formaldehyde and hydrogen peroxide gas plasma may be used for the sterilization of invasive flexible endoscopes (e.g. some choledochoscopes). Ethylene oxide is classified as a human carcinogen. These agents are suitable for the sterilization of some reusable heat-labile accessories.

Long cycle times render these methods impractical during routine gastrointestinal endoscopy lists. Furthermore sterilization is not considered necessary for decontaminating standard flexible GI endoscopes; high level disinfection using the agents discussed earlier in this section is sufficient.

When you need to change your disinfectant

- Carefully cost the change bearing in mind the use, concentration, stability and additional equipment required for processing.
- Ensure the processed items are thoroughly cleaned, and that the disinfectant manufacturers' recommended contact times are achieved, unless alternative advice from professional organisations is available.
- Ensure compatibility between endoscope brand, AER and the chosen disinfectant.
- Establish what is required in terms of COSHH regulations (e.g. ventilation, personal protective equipment) and ensure that these are included in the costing.

6. Automated Endoscope Reprocessors (AER)

These are essential for decontaminating all flexible endoscopes following manual cleaning. They protect the user from hazardous reprocessing chemicals such as disinfectants. All AERs should have been validated and tested in accordance with the guidance provided in the DoH Estates and Facilities HTM publications and relevant standards where available (36). AER should include flow monitoring for each individual channel to detect blockages.

It is essential that these machines are properly maintained and should be disinfected at the start of each working day employing, where possible, the AER's self disinfection cycle. It is recommended that thermal disinfection, or an agent other than that used for endoscope disinfection is used to disinfect the machine. Care should be taken to ensure that all disinfectants used are compatible with the AER, and are employed at the correct temperature and concentration. The microbiological quality of the rinse water and other fluids must be acceptable; it is recommended that the final rinse water is tested for its microbiological quality on a weekly basis (see below). An action plan for addressing suboptimal water quality has been produced by the Hospital Infection Society (37) and the topic has been reviewed more recently (38). The user should make daily checks of the filters and pipe work supplying rinse water. Water filters should be changed in accordance with the manufacturers' instructions, or more often if the water quality is poor (as suggested by frequent clogging of filters). Hard water can cause a deposit of limescale on internal pipe work. Advice may need to be taken from a company specialising in water treatment, and from a local consultant microbiologist.

The rinse cycle should employ bacteria-free water. This may be achieved either by using bacteria-retaining filters or by other methods (e.g. reverse osmosis). If mains water is used a water-softening and/or treatment system may be needed to prevent contamination with limescale, biofilm and micro-organisms. Some machine isolates (e.g. *Mycobacterium chelonae*) are extremely resistant to disinfection and an alternative disinfectant should be used for machine disinfection.

Some older machines have facilities for conservation of rinse water. A build-up of disinfectant will, however, occur if the rinse water is reused. This may transfer toxic residues to the endoscope and cause irritation of the patient's mucosa or, if using fibrescopes, to the endoscopist's eyes. It is recommended that rinse water is not reused.

Some special features or performance characteristics are optional but all machines should expose all internal and external endoscope surfaces to disinfectant and rinse water in accordance with the local hospital infection control committee protocols and/or national guidelines. Ideally all channel irrigation should be verified during each cycle. Instructions and training should be given by the machine manufacturers on how to connect the instrument to the washer/disinfector to ensure all channels are irrigated. It should be ensured that the connectors between endoscopes and AERs are designed to irrigate all endoscope channels, and that all channels are disinfected in accordance with endoscope manufacturer instructions. The machine should be programmable to accommodate the disinfectant contact time recommended by the disinfectant manufacturers, the Department of Health, and the professional societies such as the BSG. They should have also a cycle time compatible with the workload of the unit and run at a temperature that is compatible with the endoscopes. Care must be taken to ensure that AER are used with reprocessing chemicals that are compatible with each machine. The manufacturers of reprocessing chemicals, and the manufacturers of AER, should provide clear instructions on compatibility. Newer machines have automatic leak-testing facilities incorporated within them, but these devices are not foolproof because they do not angle the endoscope tip during leak testing, and may therefore fail to recognise positional leaks. AER manufacturers should specify in their 'intended use' statements the makes/models of endoscopes the AER is intended to reprocess, and should supply the necessary channel connection systems to allow effective reprocessing of the identified endoscopes

Older duodenoscopes do not have endoscope tips that can be detached to allow access to the elevator wire channel for cleaning. Some AERs have the capacity to deliver high-level disinfection to this channel. Users of duodenoscopes should ensure the ability of their AERs to decontaminate all internal channels, and should seek advice from their endoscope and AER manufacturers where any uncertainty exists. Additional manual cleaning and disinfection of the elevator wire channel may be necessary.

Following endoscopic examinations in patients with or at risk of vCJD, it is advisable to employ a single use disinfectant. It is also recommended that the endoscope is decontaminated separately from other endoscopes, and that the AER should be subjected to an extra rinsing cycle before the next endoscope is reprocessed. The endoscope will need to be quarantined if an "invasive" procedure has been undertaken (see Section 4). Any solid waste and/or tissue remaining within the AER should be disposed of by incineration. The outlet filter (or strainer) should also be discarded, incinerated, and replaced with a new filter. Liquid waste should be discarded by normal direct discharge from the AER.

When purchasing an AER it should be ensured that it conforms to the minimum specifications set out in the British and European Standards and any additional requirements of the UK health departments. Newly purchased AERs must be installed correctly and safely with regard to proper functioning, safety of personnel and environmental protection. It is important to ensure that the AER will irrigate all channels of each endoscope being processed, and preferably verify that such irrigation has taken place. This facility should include alerting the user to endoscope blockages or disconnections within the AER. Other features to consider when purchasing an AER include (a) a cycle counter and fault indicator, (b) a control system for use when the disinfectant produces an irritating or sensitising vapour, (c) a water treatment system which prevents recontamination of processed instruments during rinsing, (d) a reliable, effective and simple machine disinfection cycle, (e) an air drying facility to expel fluids and dry the channels of the endoscope at the end of the cycle, (f) a leak test facility, and (g) a print-out of cycle parameters which can be retained for quality assurance records.

Users are advised to review independent test reports and consult their local Authorised Persons (AP as defined in DoH Estates and Facilities publications) before purchasing AER.

7. Protecting the Operator (Box 1)

All staff involved in decontamination should wear appropriate personal protective equipment including aprons, full face visors and single use (preferably nitrile) gloves. Forearms must be protected during the endoscope dismantling and manual cleaning stages, and whilst handling detergent and disinfectant solutions. Staff should be trained in effective hand-washing in a separate sink from that used for endoscope decontamination. Care should be taken to clean and disinfect work surfaces at the end of each working day.

Staff exposed to disinfectant vapours should receive regular health surveillance. Pre-employment medical checks are still recommended even when disinfectants other than glutaraldehyde are used. Occupational health departments should enquire regarding any history of asthma, conjunctivitis, rhinitis or dermatosis. Departments should conduct a COSHH risk assessment for substances used in their hospitals' endoscopy units and, when regular staff health surveillance monitoring is indicated, lung function testing by spirometry should be carried out at the pre-employment medical visit and annually thereafter. Surveillance of employees for the appearance of symptoms should be carried out annually either by direct assessment in the Occupational Health Department or by questionnaire. Surveillance records should be retained for 40 years. If surveillance demonstrates the occurrence of occupational dermatosis or asthma, further exposure must be avoided. Staff should be encouraged to report any health problems to their line management and occupational health department.

All staff working with endoscopes should be immunised in accordance with local occupational health policy. Care must be taken in the handling of sharps, including spiked biopsy forceps. Staff should avoid the use of hypodermic needles or other sharp instruments for removing specimens from the cups of biopsy forceps. A blunt-ended needle or toothpick can be used to free the specimen.

8. Health and safety

There should always be sufficient numbers of trained staff and items of equipment to allow enough time for thorough cleaning and disinfection to take place (39). Procedures for dealing with AER malfunctions, accidents and dangerous occurrences should be documented and adhered to. Each endoscopy unit must have a policy for dealing with disinfectant or body-fluid spillage. This policy should be prominently displayed within the unit, and all staff must be trained in its implementation. Training of staff should be documented and reviewed regularly.

Given the policy of "universal precautions", which assumes that any patient may be harbouring infectious agents, there is no logic in placing "high risk" patients at the end of endoscopy lists. An exception would be a patient with Acquired Immune Deficiency Syndrome who may have resistant and/or atypical mycobacterial infection. Local infection control policies, however, may dictate that certain patients are listed at the end of the session and before the standard theatre cleaning routine. Patients with Methicillin-resistant *Staphylococcus aureus* or Vancomycin-resistant enterococci might fall into this category.

9. Practical Recommendations for Decontamination and Storage of Endoscopes (Box 2)

Manufacturers of all reusable medical instruments are required under the UK Medical Devices Regulations to provide validated reprocessing instructions for their equipment. In view of this, the Working Party has decided not to include generic cleaning and disinfection instructions in this document, but to refer users to the detailed instructions supplied by the manufacturers.

Before commencing sessions the endoscopes to be used during the list should be checked for faults. Unless they have been stored in a quality-assured purpose-built drying/storage chamber, all endoscopes must have been exposed to a cycle of disinfection in the AER not more than 3 hours prior to use. The exposure times recommended by the manufacturer for each disinfectant should be adhered to. Trusts should undertake a risk assessment exercise on the need to repeat manual cleaning of the endoscope channels prior to automatic reprocessing at the start of each list.

Care should be taken to ensure that endoscopes prepared for use are stored in a separate room from endoscopes that await reprocessing. Endoscopes should be stored in a purpose-built drying/storage chamber, or should be hung vertically in a dry and well-ventilated storage cupboard. Special care should be taken to avoid coiling of any part of the endoscope so as to reduce stasis of any droplets within the channels. All valves, seals, soaking caps, angulation locks and detachable tips should have been removed. They should be stored with their corresponding endoscope, and should not be replaced until the endoscope is next used. Valves should be dried and lubricated as instructed by the manufacturer.

There are reports of possible damage to the external surfaces of endoscopes resulting from continued exposure to ultraviolet light emitted by some brands of storage cabinet. Designs of storage chamber that do not emit ultraviolet light are therefore preferable.

10. Quality assurance of decontamination, drying and storage of endoscopes

A group was set up under the auspices of the Department of Health Endoscopy Team to produce a checklist that is designed to assist units in quality assurance and to facilitate external audits of decontamination practice (40). Potential points for internal audits are set out therein.

There have been several publications concerning surveillance cultures of endoscopes following decontamination. (9, 41-44). Other proposed initiatives include the use of PCR (9) and adenosine triphosphate bioluminescence (45). Nelson has pointed out the difficulties in standardising surveillance culture protocols, which are both time consuming and expensive, and may fail to detect atypical organisms. He also commented that endoscopes are not handled in a sterile fashion following decontamination, and that the presence of skin and environmental contaminants cannot be interpreted as a failure of disinfection (6).

Quality assurance of AER requires regular testing in accordance with the current relevant HTM. There should also be annual testing for atypical mycobacteria, with culture plates incubated at 30°C as well as 37°C. More frequent testing for atypical mycobacteria may be prudent in tertiary respiratory disease centres and/or units managing a large number of patients with HIV infection. Annual testing for endotoxin has been suggested (3, 37) but there is no real evidence to support this additional step in non-sterile endoscopy practice.

Purpose-built drying/storage chambers have recently come onto the market. These are designed to deliver high efficiency particulate filtered air to the internal channels of the endoscope at the appropriate temperature and flow rate. According to the manufacturers, their use avoids the need for endoscopes to undergo early morning repeat decontamination cycles. One endoscope manufacturer has reported damage to endoscope insertion and light guide tubes from the ultra-violet light used in some brands of these chambers and has declared UV illumination to be incompatible with its endoscopes. Units considering purchasing these chambers should therefore discuss compatibility with their endoscope manufacturer, as well as involving their infection control and decontamination officers in scrutinising the microbiological and safety data supplied by the manufacturers.

11. Cleaning and Disinfection of Accessories

This topic was addressed by an earlier BSG Working Party (46). Increasingly the accessories that are passed via the working channel of endoscopes are single use. These include cytology brushes, polypectomy snares, injection needles and most ERCP accessories. Single use balloons are widely used as an alternative to bougies for dilatation, and are now available for forced pneumatic balloon dilatation in patients with achalasia.

The trend towards single use biopsy forceps has been accelerated by the discovery of vCJD within the gut lymphoid system. Since then there has been a case report of apparent transmission of *Trichosporon asahii* oesophagitis by reused forceps (47). The Working Party now recommends that endoscopy units in the UK should be employing single use forceps. Indeed it has been suggested that single use

biopsy forceps may be more cost-effective than their reusable counterparts (18). It is also recommended that, where single use accessories are available, these should be chosen over reusable accessories. Reusable accessories that are passed into the gastrointestinal tract (e.g. bougies) need to be tracked, and a register kept on previous patient uses.

The recommendation to move towards single use accessories has been reviewed by the National Institute for Health and Clinical Excellence. Whilst its experts do not consider that it is cost-effective to choose single use accessories for gastrointestinal endoscopy, it is conceded that once-only usage is the only means of eliminating all risk of transferring infection by way of accessories from one patient to another (48).

Accessories that are not passed through the working channel of endoscopes, such as water bottles and bougies, are normally marketed as reusable. Autoclavable accessories should be chosen whenever possible. Argon plasma coagulation catheters are now marketed as single use, but other therapeutic devices passed via the endoscope working channel (such as heater probes) are reusable and can be autoclaved. Because autoclaving is not reliable in eliminating prion particles, heater probes and other reusable accessories must be discarded after any invasive therapeutic procedures in patients with established or suspected vCJD, or risk factors for vCJD (annex F).

The Medical Devices Agency Bulletin DB2006(04) (49) advises on potential hazards, clinical and legal, associated with reprocessing and reusing medical devices intended for single use. Users who disregard this information and prepare single use items for reuse without due precautions may be transferring legal liability for the safe performance of the product from the manufacturer to themselves or their employers.

12. Staff training and competencies

The 2006 Health Act emphasises the need for staff to be trained in decontamination processes and to hold appropriate competencies for their role. It decrees the need for monitoring systems to ensure that decontamination processes are fit for purpose and meet required standards. The theme of prevention of healthcare associated infections has been developed further following the Act (50).

All staff undertaking endoscope decontamination should be trained to the appropriate standard. The requirements are set out in competency END 21 in www.skillsforhealth.org.uk. Training should include an awareness of the channel configuration of all endoscopes and of the AERs and available irrigation adaptors. Staff training programmes should be implemented and documented.

Out of hours endoscopy should not be done unless there is an endoscopy assistant available who has been trained in decontamination practice.

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Box 1: Personnel Protection during Endoscope Decontamination (Ref. 50)

1. Wear long-sleeved waterproof gowns. These should be changed between patients.
2. Use nitrile gloves which are long enough to protect the forearms from splashes.
3. Goggles prevent conjunctival irritation and protect the wearer from splashes.
4. Disposable charcoal-impregnated face masks may reduce inhalation of vapour from disinfectants, but experience with them is not yet widespread.
5. An HSE-approved vapour respirator should be available in case of spillage or other emergencies. It should be stored away from disinfectants as the charcoal adsorbs fumes and respirators should be regularly replaced.

Box 2: Ten Steps in Endoscope Decontamination

As soon as possible after use:

1. Wipe down insertion tube
2. Flush air/water channels
3. Aspirate water through biopsy/suction channel
4. Dismantle detachable parts (e.g. valves)
5. Perform a leak test
6. Manually clean air/water and suction valves prior to decontamination (or autoclaving if manufacturer sanctions this)
7. Manually clean with enzymatic detergent followed by rinsing
8. Disinfect and rinse in an automated reprocessor, with detachable parts alongside
9. Dry
10. Store appropriately

Box 3. Ten Top Tips in Endoscope Decontamination

(imported from Medicines and Healthcare products Regulatory Agency bulletin 2005: www.mhra.org.uk)

- 1. Compatibility**
Ensure compatibility with the existing hospital decontamination processes, including compatibility with the washer disinfectant, when purchasing.
- 2. Instructions**
Ensure that all equipment is operated and controlled in accordance with the manufacturers' instructions.
- 3. Identification**
Identify all endoscopes and washer disinfectants used in the hospital to ensure they are being maintained and that the correct decontamination process is being used.
- 4. Channel connection**
Check the number of channels in each endoscope and ensure that they can all be connected to the washer disinfectant using the correct connectors/connection sets provided by the manufacturer.
- 5. Manual cleaning**
Ensure endoscopes and accessories are manually cleaned prior to processing in a washer disinfectant including the flushing of all channels even if they have not been used during the procedure.
- 6. Chemical compatibility**
Use only chemicals compatible with the endoscope and their accessories and at the correct concentration as recommended by the manufacturer throughout the decontamination process.
- 7. Process validation**
Use only validated processes following guidance in NHS Estates HTM 2030 Washer Disinfectants, MHRA Device Bulletin DB2002(05) and MAC Manual on Decontamination
- 8. Decontamination: Preventative maintenance**
Have a regular planned preventative maintenance in place with records kept on each washer disinfectant.
- 9. Staff training**
Ensure all staff, including new staff, involved in the decontamination process are fully trained and that this training is kept up to date as appropriate. An e-learning course is available from the National Decontamination Training Programme (<http://decontaminationtraining.nhsestates.gov.uk>) which includes a module on endoscopy. In addition endoscope manufacturers run courses in decontamination.
- 10. Incident reporting**
Report any equipment problems relating to endoscope, endoscope washer disinfectant or associated chemicals to the MHRA via our website www.mhra.gov.uk or e-mail: aic@mhra.gsi.gov.uk or telephone 020 7084 3080. Report identified problems with any decontamination process to the local consultant in communicable disease control (CCDC) at your local health protection unit.

TABLE 1: INSTRUMENT DISINFECTANTS: PROPERTIES

Disinfectant	Microbicidal Activity				Stability	Inactivation by organic matter
	Spores	Mycobacteria	Bacteria	Viruses		
Glutaraldehyde 2% (no longer used in UK)	Moderate 3 hours	Moderate 20 mins	Good <5 mins	Good <5 mins	Moderate (e.g. 14-28 days)	No (fixative)
Ortho-phthalaldehyde (0.55%)	Poor >6 hours	Good <5 mins	Good <5 mins	Good <5 mins	Moderate (30 days)	No (fixative)
Peracetic acid 0.2 - 0.35%*	Varies 10 – 20 mins	Varies 5 – 20 mins	Good <5 mins	Good <5 mins	No (1-3 days)	No
Chlorine dioxide	Good 10 mins	Good <5 mins	Good <5 mins	Good <5 mins	No (1-5 days)	Yes
Superoxidised water	Good 10 mins	Good <5 mins	Good <5 mins	Good <5 mins	No (< 1 day)	Yes

* activity varies with concentration of product

Summary of Recommendations

Key To Grading Of Recommendations

- A. Recommendation based on at least one meta-analysis, systematic review, or a body of evidence from RCTs.
 - B. Recommendation based on high quality case control or cohort studies with overall consistency or extrapolated from systematic reviews, RCTs or meta-analyses.
 - C. Recommendation based on lesser quality case control or cohort studies with overall consistency or extrapolated from high quality studies.
 - D. Recommendation from case series or report and expert opinion including consensus.
-
- 1. Decontamination of endoscopes should be undertaken at the end of each endoscopy list and between patients by trained staff in dedicated rooms. These staff should understand the varied design of endoscopes and the need to ensure the cleaning of auxiliary channels such as water, exposed elevator wire and balloon inflation channels in endoscopic ultrasound probes. **C.**
 - 2. During lists and between patients a process of thorough manual cleaning with a low foaming enzymatic detergent which is compatible with the endoscope is an essential step before endoscope disinfection. **C.**
 - 3. All accessible channels of endoscopes should be exposed to this detergent, which should be brushed through using single use purpose built cleaning devices. These should have an appropriate length and diameter for each endoscope channel. **D.**
 - 4. The use of automated endoscope reprocessors is mandatory; manual disinfection is unacceptable. **D.**
 - 5. An effective disinfectant which is compatible with the endoscope and automated endoscope reprocessor should be used in decontamination. **C.**
 - 6. Units should move away from the use of aldehyde-based disinfectants due to their fixative properties. **D.**
 - 7. A record should be kept of the model and serial number of each endoscope used (including loan endoscopes) and each reusable accessory used for each patient. This is important for any future contact tracing when possible endoscopic disease transmission is being investigated. **D.**
 - 8. It is essential that all reprocessing stages are included after every use of the endoscope, and that none are omitted. It is also essential that all channels of all endoscopes are reprocessed after every use of the endoscope, even if the channels were not used during the preceding patient procedure. **C.**
 - 9. Endoscopy should be avoided whenever possible in patients with suspected or confirmed vCJD. **D.**
 - 10. Quarantining of endoscopes becomes necessary following the performance of invasive endoscopic procedures (including unsheathed biopsy) in patients deemed at risk of harbouring vCJD. **D.**
 - 11. When percutaneous feeding gastrostomy or jejunostomy is required in patients at risk of vCJD, or suspected or confirmed vCJD, a modified technique is needed in order to avoid contaminating the working channel of the endoscope, or the feeding tube should be deployed by radiological or surgical means. **D.**

12. "Single use" accessories must be used in preference to reusable accessories whenever a single use option is available. This applies to endoscopic biopsy forceps, guidewires, therapeutic accessories and devices used for manual cleaning. In circumstances where only a reusable accessory is available, a version that can autoclaved is preferred. Reusable accessories must be subject to tracking, both for patient use and for decontamination processes. **D**.
13. Rubber biopsy port caps should be discarded after any endoscopic procedures that involve passage of biopsy forceps or other accessories through the valves. Air-water and suction valves, and other detachable accessories, should be cleaned manually, then decontaminated with their corresponding endoscope, keeping all components together as a unique set. **D**.
14. Health surveillance of staff is mandatory and should include a pre-employment enquiry regarding asthma, skin and mucosal sensitivity problems and lung function by spirometry. Occupational health departments should conduct a COSHH risk assessment and draw up local staff surveillance policies which may include annual health questionnaires and spirometry. **D**.
15. All health care workers involved in endoscopic practice should have been immunised in accordance with local occupational health policy. **B**.
16. Staff carrying out endoscope decontamination should wear gowns and single use gloves which should be changed between each endoscope decontamination cycle. Eye and face protection is essential. Staff should cover wounds and abrasions. **D**.
17. Safe working practices in the decontamination area of each unit should be written down and understood by all staff. **D**.
18. When transporting endoscopes to and from areas outside the endoscopy unit, they must be transferred in a covered rigid receptacle. **D**.
19. If an emergency endoscopic procedure is performed out of hours, an assistant with specialist knowledge of endoscopes and their decontamination must be available. **D**.
20. Bacteria-free water should be used in the rinse cycle of automated endoscope reprocessors. To achieve this water can be passed through bacteria retaining filters. It is recommended that the final rinse water from each reprocessor should be confirmed as free of micro-organisms on a weekly basis. **D**.
21. Each endoscopy unit must have a policy for dealing with disinfectant spillage. This policy should be agreed with local health and safety advisors and should be prominently displayed within the unit. All staff must be trained in its implementation. **D**.
22. Every unit must have a protocol for dealing with body fluid spillage. The written policy should be agreed with the local infection control team. **C**.
23. Disinfectants used in automated endoscope reprocessors must be used at the correct temperature according to the manufacturer's instructions. **C**.
24. Manufacturers of purpose-built endoscope drying/storage chambers claim that their products obviate the additional cycle of decontamination at the start of each working day. Purchasers should discuss the quality assurance data supplied by the manufacturers with their infection control team and decontamination managers before purchase. These staff may concur that the early decontamination cycle may be waived provided that endoscopes have undergone a full reprocessing cycle within the preceding 72h. **C**.

25. With the exception of the scenario outlined in the preceding recommendation, endoscopes to be used each day should have been exposed to a cycle of automated reprocessing not more than three hours prior to use. Trusts must undertake a risk assessment as to the need for manual cleaning prior to automated disinfection at the start of the day. **D.**
26. Endoscopes should be stored in a purpose-built drying/storage chamber or left hanging vertically in a designated dry and well-ventilated storage cupboard. All detachable components should have been previously removed and should not be replaced until the endoscope is next used. **D.**
27. Given the “universal precautions” for endoscope decontamination there is little logic to placing “high risk” patients at the end of procedure lists. The exceptions would be patients known to have atypical mycobacterial chest infections. Nonetheless local infection control policies may dictate that patients with meticillin-resistant *Staphylococcus aureus* or other resistant organisms should be examined after other patients and before the final theatre cleaning is carried out. **D.**

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