

# **BSG GUIDANCE ON 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. There should be one way flow of endoscopes between dirty and clean areas to prevent cross contamination. Best practice is that there should be physical separation of dirty and clean areas, each with their own staff.
2. Staff training programmes should be implemented and documented. Training should include an awareness of the channel configuration of all endoscopes, manual cleaning procedures and of the endoscope washer disinfectors (EWD) and available irrigation adaptors.
3. 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. Where appropriate quality assurance data is available, the use of drying/storage cabinets may obviate the need for repeat endoscope reprocessing at the start of each list.
4. Thorough manual cleaning with a compatible medical grade CE marked low foaming neutral detergent, including the brushing and flushing of all accessible endoscope channels, must be undertaken before automated endoscope disinfection within an EWD. This routine must be undertaken during lists, between patients and after each patient examination.
5. Units should no longer be using aldehyde- and alcohol-based disinfectants because of their fixative properties, which in theory could anchor prion and other protein within endoscope channels. Units should employ either single use disinfectants or purpose-designed washer disinfectors that generate single use biocides.

6. All detergents and disinfectants must be approved for use by the EWD manufacturer, and used at the correct temperature and concentration in accordance with the manufacturers' instructions. Some manufacturers recommend the use of test kits or strips for reusable disinfectants in order to ensure the optimal activity of their product. Machine testing should include the accuracy and reproducibility of the dosing system.
7. It is important to ensure that both the endoscope and EWD manufacturers have approved the chosen detergent and disinfectant as being compatible for use with their products.
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. Endoscope washer disinfectors (EWD) 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 alcohol is no longer recommended.
11. Water used in an EWD 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 EWD and tested weekly for its microbiological quality in accordance with the current relevant EN Standard, Health Technical Memorandum (HTM) or Choice Framework for local Policies and Procedures (CFPP 01-06).
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 EWD and cycle parameters used in decontaminating that endoscope should also be kept.

13. The agent of variant Creutzfeldt-Jakob disease (vCJD) is believed to be resistant to all forms of conventional sterilisation. The risk of transmission of this agent is 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. 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". If an invasive procedure is undertaken in a patient with definite or possible vCJD (or in a patient at increased risk through receipt of labile blood products such as red cells from a donor who later developed vCJD) it will necessitate the subsequent quarantining of the endoscope used.
15. The performance of an "invasive" procedure (defined in 14 above) in a patient at risk of vCJD due to receipt of pooled plasma concentrates is no longer deemed to confer a high risk of endoscope contamination. A single quality assured decontamination cycle according to these guidelines is considered sufficient, but the endoscope should be decontaminated separately from others with a single-use disinfectant. There is no longer a requirement to quarantine the endoscope provided that routine traceability data can demonstrate thorough reprocessing.
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 EWD, keeping the valves and endoscopes together as a traceable unique set.

18. Due to the increase in demand for endoscopy, and the implementation of national quality standards for patient privacy and dignity, many units have had to expand in limited space, with the result that decontamination facilities have been moved to a location away from the endoscopy unit. Used endoscopes and their internal channels must be kept moist during transfers to remote decontamination facilities and until reprocessing. In addition there must be electronic tracking of endoscopes between units and remote facilities. By contrast the channels of reprocessed endoscopes must be kept dry until the time of next patient use.
19. Health surveillance for staff exposed to disinfectants should be considered, in consultation with occupational health departments. Occupational health records should be retained for 40 years.
20. 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.
21. Out of hours endoscopy should not be done unless there is an endoscopy assistant available who has been trained in decontamination practice. If the decontamination facility is remote from the endoscopy unit it must be able to accept endoscopes for reprocessing every day of the week.
22. Endoscopes used for Natural Orifice Transluminal Endoscopic Surgery (NOTES) and choledochoscopes should undergo some form of sterilisation process. High level disinfection is not sufficient. Reusable sheathed accessories passed up the bile duct also require special attention (See Section 8).
23. 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) 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.
24. A summary guideline on avoiding pitfalls in endoscope decontamination practice has recently been updated by the MHRA. A link to this is given in Reference 49.

## 1. Introduction and Historical Perspective

Flexible endoscopes are complex reusable instruments that require unique consideration with respect to decontamination. Their external surfaces and internal channels for air, water, aspiration and accessories are all potentially 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. Most flexible endoscopes are classed as “semi-critical devices” as they come into contact with mucous membranes during use and present a moderate degree of infection risk if contaminated at the time of use (1). The process of flexible endoscope decontamination is referred to as “high level disinfection”. This is the term given to a process that eliminates or kills all vegetative bacteria, mycobacteria, fungi and viruses, except for small numbers of bacterial spores.

Flexible endoscopes that enter normally sterile body cavities are regarded as “critical devices”. Examples include choledochoscopes and those used for NOTES (natural orifice transluminal endoscopic surgery). These must go through a process of sterilisation that does not damage the endoscope (see Section 5f below).

The BSG first published recommendations on endoscope decontamination practice in 1988, and the recommendations from the fourth working party appeared in Gut in 1998 (2). In 2002 a fifth working party reconsidered the recommendations for decontamination of endoscopes and their devices, prompted by a Health and Safety Executive report that safer alternatives to glutaraldehyde should be used within health care settings.

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 England in 2006 and updated in 2010. 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 decreases 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 6<sup>th</sup> Working Party met in 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 variant Creutzfeldt-Jakob disease (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. Updated guidelines were circulated to all BSG Members and UK National Health Service endoscopy units and displayed on the BSG website ([www.bsg.org.uk](http://www.bsg.org.uk)).

Two Working Party meetings have taken place since 2008, prompted by the following developments: (a) a rethink on the theoretical risk of transmission of vCJD by endoscopy or surgery (at the time of writing there are no known cases of transmission of the infective agent of vCJD by means of endoscopy or surgery); (b) implications arising from a trend towards decontamination at sites remote to endoscopy units; (c) new endoscope technologies (Natural Orifice Translumenal Endoscopic Surgery – NOTES, direct cholangioscopy – Spyglass system (Boston Scientific) and developments in endoscopic ultrasound; (d) reports of contact dermatitis linked to the use of enzymatic detergents; (e) developments in training and workforce for flexible endoscope decontamination. Also included herein is a table setting out prevailing guidelines in the field, giving their remit, applicability and any linked audit tools (Table 1).

## **2. Transmission of Infection at Endoscopy**

A guiding principle for decontamination is that of standard 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 (5-11). 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 EWD, the use of substandard disinfectant, or inadequate drying and/or storage of endoscopes (12,13).

The ability to form biofilms allows micro-organisms to survive under conditions of drying, chemical or antibiotic exposure. An outbreak of post-ERCP sepsis with multi-resistant *Pseudomonas aeruginosa* was related to biofilm development inside endoscope channels (11). A recent report of an outbreak of multi-drug resistant *Klebsiella pneumoniae* highlights the potential dangers of not adhering to decontamination recommendations and training (12). A detailed review on endoscopy-associated infection has been published (14). This inquiry identified that inadequate decontamination procedures and equipment malfunction were two leading causes of post-endoscopic infection and contamination. It was suggested that improved quality control systems could prevent over 90% of such infections.

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 used to be 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 (6).

Three types of micro-organisms have merited particular attention during the last two decades:

- 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 (15).
- c. *Pathological Prions including Creutzfeld 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 Section 4.

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* (16). Another example is the acquisition of *Herpes simplex* ophthalmitis following oesophageal biopsy (17). 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 local infection control policies should be adhered to, including cleaning of the procedure room after examining certain at-risk patients. Infection control managers often mandate the scheduling of patients with meticillin-resistant *Staphylococcus aureus* (MRSA) at the end of lists.

### **3. Decontamination of endoscopes – general considerations.**

**a) Definitions:** Sterilisation is defined as the complete destruction of all micro-organisms including bacterial spores (1). 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 a pre-cleaning routine in the procedure room before the endoscope is disconnected from its stacking system, brushing with a purpose-built single-use cleaning device, and exposure of all external and accessible internal components to a low-foaming medical grade detergent known to be compatible with the endoscope;
- b. automated disinfection, followed by rinsing and drying of all exposed surfaces of the endoscope.

It is essential that all reprocessing stages including leak testing are undertaken after every use of the endoscope, and that none are omitted. It is also mandatory that leak testing is carried out after every procedure. All channels of endoscopes must be 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.

**b) Process:** This is summarised in the flowchart (Figure 1) together with the basic anatomy of a flexible endoscope (Figure 2). 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 (and any auxiliary channel should be irrigated with detergent, 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. Excess fluid should then be expelled from all channels by flushing with air. 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. It is essential to follow the endoscope manufacturer's recommendations with regard to timing, and amounts of air and fluids employed at each step.

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 accessories 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. The practice of ultrasonic cleaning of valves in batches is not acceptable .

The third stage is *manual cleaning* and rinsing of all exposed internal and external surfaces. This should be undertaken within a sink in the "dirty" section of the decontamination area. A low-foaming neutral detergent that has been specifically designated for medical instrument cleaning should be used at the appropriate dilution according to the manufacturer's instructions. All detergents and disinfectants must be approved for use by the EWD manufacturer (see Decontamination Alert 2013 – 18). The detergent should be aspirated from a clean bowl, separate from the contents of the sink used for manual cleaning. Electronic devices that pump detergent through endoscope channels are also available.

Previous editions of this guidance have recommended the use of enzymatic detergents based on their theoretical ability to digest mucus and other biological material from within narrow endoscope channel lumens. In the CFPP 01-06 guidance for health service units in England no preference for enzymatic detergents is expressed (19). A move away from enzymatic detergents has been prompted by reports of occupational asthma and skin sensitization (20). Whatever detergent is employed it must be acceptable to the endoscope manufacturer and it should be used according to their instructions. Some manufacturers recommend purpose-built injection tube sets that connect with each channel to facilitate cleaning. Consideration should be given to using different detergents for the manual cleaning and automated reprocessing steps. 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 endoscope washer disinfectant (EWD). 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 EWD, and reprocessed simultaneously with the endoscope. Users should be advised to employ devices that are CE-marked for the grouping of detachable components within the EWD. It is important to note that even the use of the most modern and sophisticated EWD does not replace the need for prior thorough manual cleaning including brushing of all working channels. Disinfectants used in endoscopic practice are discussed in more detail in Section 5 and Table 2.

The process of decontamination should be concluded with *further rinsing* with sterile or filtered water, followed by *proper drying* of each endoscope. Purpose-built drying/storage chambers deliver high efficiency particulate filtered air to the internal channels of the endoscope at the appropriate temperature and flow rate. Their use may avoid the need for endoscopes to undergo early morning repeat decontamination cycles. Cabinets vary in their quality assurance concerning maximum duration of storage before a repeat reprocessing cycle becomes necessary, but 72hr is typical (see Section 7 below).

**c) Infrastructure:** Decontamination should be done in a dedicated area with atmospheric extraction facilities that have been properly maintained. Guidance on ventilation in healthcare premises is given in HTM 03-01 (21). There must be separate areas for the receipt of endoscopes following patient use (dirty area) and for the storage and drying of endoscopes following automated reprocessing (clean area). To avoid cross contamination of clean endoscopes it is recommended that separate teams of staff work in these areas who do not cross between them. One-way flow of

endoscopes from dirty to clean areas should be assured. To this end many units employ “pass-through” EWDs with separate hatches for placing and connecting dirty endoscopes and collecting reprocessed scopes into the clean area.

There is a growing trend for locating decontamination facilities away from endoscopy units so as to allow more space for clinical areas and improved patient privacy. The preliminary cleaning routine should take place within the endoscopy unit, and endoscope channels must be kept moist during transfer to the reprocessing facility. Endoscopes should be transported in a sealed humid environment. In practice this means they should be packaged as soon as possible after manual cleaning and flushing, but water should not be poured into the container so as to be lying freely. Prevailing regulations on the transport of contaminated goods must be adhered to; this includes the clear labelling of packaging as “used medical device/equipment” (22)

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. A lockable mobile trolley is advisable for the transportation of multiple endoscopes from a unit to a centralised decontamination facility, especially if the trolley is to be left unattended in a publicly accessible area. The receptacle will itself need to undergo a separate cleaning and decontamination process.

Hospitals undertaking endoscopy outside normal working hours will need to ensure that any remote facility is able to accept endoscopes for reprocessing on weekend days and public holidays. Another consequence of a remote facility is the likelihood of longer turnaround times for reprocessing before next patient use. Thus the unit is likely to require a larger compliment of endoscopes to support each list. Endoscope drying and storage facilities need to be present both in the endoscopy unit and in the remote facility. Any cleaned endoscope that remains outside such storage facilities for longer than 3hr before next patient use will need to be reprocessed a second time. In other words there is a three hour limit that includes (i) the transportation time between reprocessing or leaving storage at the remote site and the return to storage at the endoscopy unit; PLUS (ii) the time between storage and next patient use in the unit itself.

There are alternative vacuum packing systems available for transportation, but if this method is employed to return a clean endoscope to an endoscopy unit it must be ensured that all channels have been thoroughly dried before packaging. An electronic traceability system is mandatory for units relying on a remote decontamination facility.

**d) Traceability:** 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, an infectious disease such as vCJD. Serial numbers of all endoscopes and accessories must be recorded for each patient examined, and endoscopes must be properly tracked through their decontamination processes.

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. It should be possible to demonstrate that an endoscope has been through a full reprocessing cycle prior to each patient use. Documentation should also be able to demonstrate when an endoscope has been kept in a storage cabinet and then been reprocessed on exit.

The detachable components should be kept with their corresponding endoscope, forming a unique set. A record of the decontamination process should be retained. There must also be a means of tracking each patient use of any reusable endoscopy accessories. The tracking system operating in each unit should be subject to regular audit.

**e) Other considerations:** 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.

The handling of loan endoscopes requires special consideration. They may arrive without detachable components (valves), and units may be expected to provide these. Loan scopes need to be reprocessed prior to first patient use and embraced within the tracking process. Disinfectants used in the unit must be compatible with loan endoscopes. It is advised that valves are removed and discarded before the endoscope is returned to the manufacturer.

National guidelines (for example CFPP 01-06 in England) (19) and local decontamination lead personnel should be consulted about the choice of disinfectants and detergents. Advice from endoscope and EWD manufacturers should

also be sought, bearing in mind that service contracts and guarantees may not be honoured if incompatible disinfectants and detergents have been employed.

The decontamination of endoscopy equipment is a specialised procedure that should only be carried out by personnel who have been trained for the purpose and who have an understanding of the principles involved. 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.

#### **4. Relevance of Transmissible Spongiform Encephalopathies (CJD) to Endoscopic Practice**

**a ) Background:** Creutzfeldt-Jakob disease (CJD) is a rare and ultimately fatal degenerative brain disease that falls within a group of neurological disorders known as the transmissible spongiform encephalopathies (TSEs). Otherwise known as prion diseases, they can affect both animals (scrapie in sheep, BSE in cows) and man. The precise nature of the transmissible agent is unknown, but is believed to be an abnormally folded form of a host-encoded prion protein. The normal prion protein (PrP<sup>c</sup>) is expressed in many tissues, but is concentrated within neurones in the central nervous system (CNS). The abnormal form of the protein (PrP<sup>Sc</sup>) 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 that was first reported in 1996. It exhibits a unique neuropathological phenotype (23), and affects mainly young adults. The incubation period for vCJD could be as long as 30 years.

Fortunately earlier fears of large numbers of vCJD deaths have not been realised, and the incidence has been in decline for several years. However, there is evidence that many more people might be infected, while not showing any symptoms (24). If these people are infective, the risk of 'secondary' (person-to-person) transmission could be greater than implied by the smallish number of cases seen so far. In particular, vCJD can be transmitted via blood transfusion (25), and could in theory be passed on by the re-use of surgical instruments. Thus invasive procedures (such as

endoscopy with biopsy) have the potential to transmit the disease from affected asymptomatic individuals in the incubation phase.

The differing distribution of the PrP<sup>Sc</sup> in the body in sporadic and vCJD reflects their different pathogenesis. In sporadic CJD, prion infectivity is largely limited to the CNS and retina. Gastrointestinal endoscopy is not considered to be a potential 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<sup>Sc</sup>, and may contain significant levels of infectivity during the incubation period (26). The abnormal form of the prion protein can be detected in rectal tissue and Peyer's patches (27,28). Since lymphoid follicles and germinal centres are widely distributed in the gastrointestinal tract (and are often biopsied), endoscopic interventions in patients who are incubating vCJD could expose the instrument (and particularly the biopsy forceps) to PrP<sup>Sc</sup>.

Risks of transmitting vCJD from one person to another depend 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.

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 (29,30).

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. 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.

**b) Individuals at risk** of vCJD include people (e.g. those with haemophilia) who received plasma based concentrates between 1980 and 2001, and also a small group who received labile 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.

**c) Practical Guidance:** Until recently it was advised that any invasive procedure in any "at risk" patient necessitates the quarantining the endoscope. Given the absence of any known transmission of vCJD by means of endoscopy or surgery, and the dramatic fall in the incidence of vCJD, the UK Advisory Committee for Dangerous Pathogens revised its risk assumptions in 2012 (31). The updated guidance means that quarantining of the endoscope is nowadays rarely necessary. It still applies following the performance of an invasive endoscopic procedure in a patient with definite or probable vCJD, or someone regarded as presumed infected having received labile blood products (such as whole blood, red or white cell concentrates) from a donor who subsequently developed vCJD. Temporary quarantining is also indicated following invasive endoscopy in a patient with undiagnosed neurological illness when vCJD cannot be excluded, or where subclassification of CJD infection is still pending. (Table 3). 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.

If it becomes necessary to quarantine an endoscope it should be decontaminated as below, then dried in a drying cabinet overnight before being transferred to its original suitcase container. The outside of that container should be clearly labelled to show that the endoscope is in quarantine and not suitable for use in examining any patients other than the index patient.

If invasive endoscopy has been performed in any patient with or at increased risk of vCJD the endoscope used should be reprocessed singly before being quarantined. If a contamination risk is confirmed, the endoscope should be either destroyed or retained for dedicated re-use for the same patient. For some procedures, it may be possible to shield the working channel of the endoscope from contamination by means of a disposable sheath. Once the procedure is completed, the tip of the accessory (e.g. biopsy forceps) is withdrawn into the sheath, before the tip of the sheath is cut off and, like the remainder of the sheath, is later destroyed by incineration.

It is recommended that single use disinfectants should be used for endoscopes that have been used in any "at risk" individual, and that such endoscopes should be decontaminated separately from any other endoscope. Whilst the dilutions and flows of fluids preclude any significant risk of contaminating the AER itself, it is recommended that the endoscope washer disinfectant should be put through an empty self-disinfection cycle after it has been used to decontaminate an endoscope that has been used for the performance of an invasive procedure in an at-risk patient.

Rigid metal sigmoidoscopes and proctoscopes should be thoroughly cleaned and then autoclaved. 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 (31)

## 5. Disinfectants

The ideal disinfectant would be:

- Effective against a wide range of organisms (bactericidal, mycobactericidal, fungicidal, virucidal and sporicidal)
- Active against prion proteins (though no such agent that is suitable for endoscope reprocessing is known to exist)
- Compatible with endoscopes, accessories and endoscope washer disinfectors.
- Non-irritant and safe for users.
- Environmentally friendly for disposal.

Other factors that 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 EWD, 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 EWD 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 8). A spillage procedure and kit must be available within the department.

The widely used disinfectants were reviewed in detail elsewhere (32) and are briefly discussed below. Their properties are shown in Table 2.

### a. Aldehyde-based disinfectants:

A formerly widely-used glutaraldehyde-based disinfectant (Cidex ®) was withdrawn from the United Kingdom market in 2002, due to occupational safety concerns such as asthma and contact dermatitis. A further problem

with aldehyde-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.

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, marketed as reusable and stable at a wide pH range. It has better bactericidal and mycobactericidal activity than 2% glutaraldehyde.

Ortho-phthalaldehyde can stain skin, instruments, clothing, and surfaces. The manufacturers of Cidex OPA ® recommend the daily use of OPA test strips to monitor the activity of reused batches of disinfectant solution. The use of OPA and other aldehydes is no longer recommended in the UK.

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 (33-37). 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. Electrolytically generated hypochlorous acid (EGHA)

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 biocide has the advantage of being non-toxic to biological tissues, and non-irritating to the respiratory tract, eyes, and skin. The "Sterilox ®" system automatically changes and regenerates the active biocide, hypochlorous acid, every 23hr within an enclosed chamber.

EGHA is rapidly effective (38-41) but again activity and compatibility with endoscopes can vary according to 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 (42,43). 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 sterilization 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, storage life and additional equipment required for processing.
- A single use disinfectant preparation is strongly recommended in the UK.
- 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, EWD 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.
- Liaise with the disinfectant manufacturer about the quality of diluent water required.

## 6. Endoscope Washer Disinfectors (EWD)

These are essential for decontaminating all flexible endoscopes following manual cleaning. They are far more effective than manual cleaning and also protect the user from hazardous reprocessing chemicals such as disinfectants. All EWDs should have been validated and tested in accordance with prevailing national guidance, manufacturer's instructions and relevant standards where available (Table 1). EWD 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 EWD's self disinfection cycle. Some machine isolates (e.g. *Mycobacterium chelonae*) are extremely resistant to disinfectants, including glutaraldehyde. It is therefore recommended that either thermal disinfection, or use of an agent other than that used for endoscope disinfection, is used to disinfect the machine. Available operating cycles on the automatic control system should provide for an EWD self-decontamination cycle to ensure that all pipework, tanks, pumps, water filtration systems and other fittings that are used to carry aqueous solutions intended to come into direct contact with the endoscope are cleaned and disinfected. The self-decontamination cycle should be user-selectable and programmable, so it can run at a time convenient to the Operator. Heat self disinfection is recommended in by International Standards Organisation (ISO 15883-4, clause 4.8.1). An EWD in which the endoscope process cycle provides for disinfection of the chamber and all piping and tanks that come into contact with the water or solutions used for cleaning, disinfecting and rinsing the load – will meet this requirement without provision of an additional self-disinfection cycle (see BS EN ISO 15883-4, clause 4.8.2).

Care should be taken to ensure that all disinfectants used are approved for use with the EWD, 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 (44) (Table 4). 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 or decontamination lead. An action plan in response to the finding of contaminated final rinse water should be prepared in conjunction with the Infection Prevention and Control Team (IPCT).

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. It is recommended that rinse water is not reused for the final rinse stage.

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 each channel irrigated should be verified during all cycles. 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 EWDs 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 EWDs are used with reprocessing chemicals that are compatible with each machine. The manufacturers of reprocessing chemicals, and the manufacturers of EWD, 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. EWD manufacturers should specify in their 'intended use' statements the makes/models of

endoscopes the EWD is intended to reprocess, and should supply the necessary channel connection systems to allow effective reprocessing of the identified endoscopes

Some EWDs have the capacity to deliver high-level disinfection to auxiliary and/or duodenoscopy wire elevator channels. Users of duodenoscopes should ensure that their EWDs can decontaminate all internal channels, and should seek advice from their endoscope and EWD manufacturers where any uncertainty exists. It should be noted that some echoendoscopes (used for endoscopic ultrasound) do not fit into all EWDs. Additional manual cleaning and disinfection of the elevator wire channel may be necessary.

Following endoscopic examinations in patients with definite or probable vCJD, or those at risk and presumed infected (a very small group at the time of writing) it is recommended that the endoscope is decontaminated separately from other endoscopes. This should be undertaken with a single use disinfectant, and the EWD 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 EWD 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 EWD.

Following an invasive endoscopic examination in patients at risk of vCJD, (as distinct from those presumed infected) it is recommended that the endoscope is decontaminated separately from other endoscopes with a single-use disinfectant. Provided that a rigorous tracked standard decontamination cycle has been carried out no further precautions are necessary.

When purchasing an EWD 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 relevant UK health departments. Newly purchased EWDs must be installed correctly and safely with regard to proper functioning, safety of personnel and environmental protection. It is important to ensure that the EWD 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 and disconnections within the EWD. Other features to consider when purchasing an EWD 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 decontamination lead and Authorising Engineer (Decontamination) before purchasing EWDs. The same advice applies to the purchase of drying/storage cabinets (below).*

## **7. Drying/Active Storage Cabinets**

Drying or active storage cabinets are recommended to supplement drying by the EWD and to store endoscopes until next patient use. They should be located either in the clean zone of the endoscope reprocessing area or in a separate clean area close to the endoscopy procedure room (but not in the procedure room itself). A wide choice of drying cabinets is available. The most commonly used design is a tall version in which all endoscope channels are connected while the scope hangs vertically. Care should be taken to ensure that the height of the cabinet is sufficient to avoid the distal tip “touching” or curling up on the “floor” of the cabinet. There are other systems of endoscope reprocessing that allow each scope to be connected separately within its own casing following manual cleaning. The scope remains within this casing during disinfection, drying and storage until next patient use. Units considering purchasing these chambers should discuss their 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.

The following query list may be helpful when comparing cabinets:

(a) Can all lumens in the endoscope be connected to a filtered air supply and the flow monitored throughout the storage time? (b) What level of filtration is used for the cabinet air supply? (c) What is the source of filtered air? Does the cabinet require an external source of filtered air? If medical air is to be used, the Authorising Engineer should be consulted to determine the impact this may have on other services supplied from the same source. (d) Does the cabinet allow internal air pressure to be monitored during its operation? (e) Can the cabinet be locked and restricted access levels provided? (f) How many endoscopes can be accommodated simultaneously within each cabinet? (g) Does the cabinet monitor each endoscope in store, record the data and indicate if the values fall short of specification or the endoscope has been in store too long? (h) Does the cabinet allow for continuation of the traceability system? (i) Has the cabinet manufacturer produced reliable data to show a stored endoscope may be directly used on a patient without

processing? (j) Which tests have been carried out to show if the cabinet dries endoscopes and keeps them free of contaminating organisms during storage and prevents any residual contamination from growing? From this data has the manufacturer recommended as the maximum safe period of storage? (k) Can endoscopes be added or removed from the cabinet without contaminating other endoscopes in the cabinet? (l) Is the cabinet easy to clean and constructed of non-porous material with sealed joints? (m) Are double-ended "pass through" cabinets required as part of the design?

If an endoscope is used infrequently it is reasonable to store it separately hanging vertically in a purpose-built cabinet (as opposed to a drying cabinet) and reprocess it prior to next patient use.

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 expose endoscope surfaces to ultraviolet light are therefore preferable.

## **8. Special Situations**

Endoscopes used for Natural Orifice Transluminal Endoscopic Surgery (NOTES) should undergo a sterilisation process prior to next use.

Sheathed accessories passed up the bile duct may be decontaminated by adapticide disinfection chemistry within a washer disinfector, but there remains potential for re-contamination during the final rinse water cycle. These probes should therefore be reprocessed by means of a higher level disinfection cycle within three hours of next patient use.

## **9. Health, Safety and Infection Control**

All staff involved in decontamination should wear appropriate personal protective equipment (Box 1) including aprons, full face visors, masks (where appropriate) 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 (45).

Staff exposed to disinfectant vapours should receive regular health surveillance. Occupational health departments should enquire regarding any history of asthma, conjunctivitis, rhinitis or dermatosis. Departments should conduct a risk assessment of 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 dermatitis 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

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) require employers to assess the risk to the health of staff by exposure to hazardous chemicals 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. Guidance on ventilation of healthcare premises is discussed in HTM 03-01 (21).

Some units employ electronic devices for pumping detergent through endoscope channels during manual cleaning. Care must be taken to avoid any contact between cables and sinks.

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 (46-48). Procedures for dealing with EWD malfunctions, accidents and

dangerous occurrences should be documented and adhered to. Each endoscopy unit must have a policy tailored to endoscopy 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 annually.

A spills kit suitable for endoscopy units should contain as a minimum the following components:

- absorbent granules/powder – to absorb liquid spills;
- absorbent sock – to contain liquid spills;
- chemical inactivator – to neutralise a chemical spill;
- Fuller’s earth – to inactivate a spill if the neutraliser is not available and soak up liquid;
- plastic apron, gauntlets and respirator/mask – personal protective equipment (PPE);
- orange bag – for containing clinical waste;
- dust-pan and brush – to sweep up granules and Fuller’s earth, if used.

Some authorities have recommended the use of disposable charcoal-impregnated face masks, but experience is limited. Periodic checks are required to ensure that all of the items within the above kit have not passed their expiry date.

Given the policy of “standard precautions”, which assumes that any patient may be harbouring infectious agents, there is no logic in scheduling “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 Meticillin-resistant *Staphylococcus aureus*, *Clostridium difficile*-associated diarrhoea or Vancomycin-resistant enterococci might fall into this category.

## **10. Practical Recommendations for Decontamination and Storage of Endoscopes (Figure 1)**

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 EWD not more than 3 hours prior to use. The exposure times recommended by the manufacturer for each disinfectant should be adhered to. Competent and operationally trained decontamination leads 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 ready for use are stored in a separate room from endoscopes that await reprocessing. Reprocessed endoscopes that are ready for use should be stored in a purpose-built drying/storage chamber. 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.

It is recommended that the Medicines and Healthcare Products Regulatory Agency (MHRA) table entitled “Top Ten Tips” is prominently displayed in all endoscopy units (49). The MHRA has also released guidelines on Managing Medical Devices which sets out some basic principles on decontamination and training (50)

## **11. Quality assurance of decontamination, drying and storage of endoscopes**

There are at least three audit tools that can be used in the peer review of endoscope decontamination practice. One was produced by the NHS Endoscopy Team and is now under the ownership of the Joint Advisory Group on GI Endoscopy (47). Another has been prepared by the Infection Prevention Society (51). More detailed testing regimens are described in local health and technical memoranda and in CFPP 01-06 (19). Potential points for internal audits are set out therein.

Quality assurance of EWD requires regular testing in accordance with the current relevant HTM/CFPP. At the time of writing weekly total viable counts of bacteria in end rinse water from EWDs is expected in all audits. There should also be annual testing for atypical mycobacteria, with culture plates incubated at 30°C as well as 37°C (Table 4). 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, 49) but there is no real evidence to support this additional step in non-sterile endoscopy practice.

There have been several publications concerning surveillance cultures of endoscopes following decontamination. (9, 52-55). Other proposed initiatives include the use of PCR (9) and adenosine triphosphate bioluminescence (56). 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). Surveillance cultures may be recommended by local microbiologists or infection control teams following any outbreak.

## **12. Cleaning and Disinfection of Accessories**

Nowadays the vast majority of 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 also available for forced pneumatic balloon dilatation in patients with achalasia.

Accessories that are not passed through the working channel of endoscopes, such as water bottles and bougies, are often marketed as reusable. Autoclavable accessories should be chosen whenever possible. Argon plasma coagulation catheters are marketed as single use, but other therapeutic devices passed via the endoscope working channel (such as heater probes) are reusable and can be autoclaved. Reusable accessories that are passed into the gastrointestinal tract (e.g. bougies) need to be tracked, and a register kept on previous patient uses. 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 (30). Any flushing devices that accompany an endoscope can be flushed with detergent, rinsed with clean water and dried with forced air (if applicable) at the end of each working day.

The Medical Devices Agency Bulletin DB2006(04) (57) 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.

### **13. 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 (45). Competencies have been set out in the Institute of Decontamination Science's educational framework (48).

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. Training should include an awareness of the channel configuration of all endoscopes and of the EWDs and available irrigation adaptors. It is essential that personnel at all levels should have a sound general knowledge of decontamination, including some knowledge of the basic elements of infection control, microbiology and process chemicals, and the potential hazards posed by these. Training in the use of personal protective equipment and the management of spillage are also essential.

Many units now employ specialist technical staff for the decontamination of flexible endoscopes. Advantages include their advanced knowledge of health and safety issues relating to endoscope reprocessing, potentially reducing the risk of cross-contamination. They can acquire and disseminate knowledge of the anatomy, functionality and decontamination requirements of the increasing variety of endoscopes available, in addition to specialist knowledge of

the EWDs used. They are best placed to lead on preparation for peer review audits of their own decontamination facilities and to participate in the peer review of other units. Moreover their presence may free qualified nursing staff for clinical duties.

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 and revalidated annually.

If an emergency endoscopic procedure is done out of hours, someone with knowledge of the endoscope decontamination process must be available to prepare the equipment, and to perform at least manual pre-cleaning following patient use. Best practice is to carry out a full endoscope reprocessing cycle in units housing decontamination facilities. When decontamination is performed off site the assistant should perform manual cleaning and arrange safe dispatch of the endoscope (discussed in Section 3c above).

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### **Box 1: Personnel Protection during Endoscope Decontamination**

1. Wear long-sleeved waterproof gowns. These should be changed between sessions within the decontamination area or on transfer between the dirty and clean area
2. Use nitrile gloves which are long enough to cover the sleeves, so as to protect the forearms from splashes. Hands should be washed or disinfected after removing protective clothing.
3. Full face visors protect the wearer from splashes to the conjunctiva.
4. Face masks may reduce inhalation of vapour from disinfectants, but should be used and disposed of according to manufacturers' instructions
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:**

#### **Medicines and Healthcare Products Recommendations on Decontamination of Medical Devices (2014)**

1. A local policy sets out the management and transport of medical devices from the point of use to the decontamination facility.
2. All items subject to inspection, service, repair, or disposal should be decontaminated beforehand, following validated methods and procedures.
3. Decontamination has been carried out in line with the manufacturer's instructions.
4. All relevant members of staff have been fully trained in decontamination protocols [[www.idsc-uk.co.uk](http://www.idsc-uk.co.uk)].
5. It is illegal to send contaminated items through the normal post
6. Ensure that single use items are disposed of and not reused even if decontamination has been attempted.

**FIGURE 1: Flowchart to summarise the flexible endoscope decontamination process**



**TABLE 1: Relevant documents on decontamination practice and clinical audit tools**

Document	Remit	Countries in which applicable	Linked audit tool
Health and Social Care Act (2011)	Code of practice on prevention and control of infections and related guidance	England	
CFPP 01-01 (2012)	Surgical instruments Part A: Formation of local policy and choices manual Part B: Common elements Part C: Steam sterilisation Part D: Washer disinfectors Part E: Alternatives to steam for sterilising reusable devices	England	
CFPP 01-06 (2012)	Flexible endoscopes: all aspects decontamination, infrastructure and QA	England	IPS (see link in Section 10)
WHTM 01-06	As above	Wales	
Health Protection Scotland guidance	Flexible endoscopes: all aspects decontamination, infrastructure and QA	Scotland	
Joint Advisory Group (The JAG)	Standards	UK (not mandated, but forms part of JAG accreditation visits)	Integral
ISO 15883	Washer disinfectors Part 1 – General requirements Part 4 – Requirements and tests for washer disinfectors employing chemical disinfection for thermo-labile endoscopes Part 5 - Test soils and methods for demonstrating cleaning efficacy	International *	
ISO 13485	Medical device quality system requirements	International *	
ISO 14971	Application of risk management to medical devices	International *	
MHRA DB 2006 (05) #	Managing medical devices (Update due 2013)	UK	
MHRA Top Ten Tips	Summary document for end users	UK	
UNECE	Transport of dangerous goods	International	

\* Adopted by European Union

# Medicines and Healthcare products Regulatory Agency

**TABLE 2: DISINFECTANTS USED FOR ENDOSCOPES AND THEIR PROPERTIES**

<b>Disinfectant</b>	<b>Spores</b>	<b>Mycobacteria</b>	<b>Bacteria</b>	<b>Viruses</b>	<b>Stability</b>	<b>Inactivation by organic matter</b>
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 5 – 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
Electrolytically generated hypochlorous acid	Good <5 mins	Good <5 mins	Good <5 mins	Good <5 mins	No	Yes

- activity varies with concentration of product

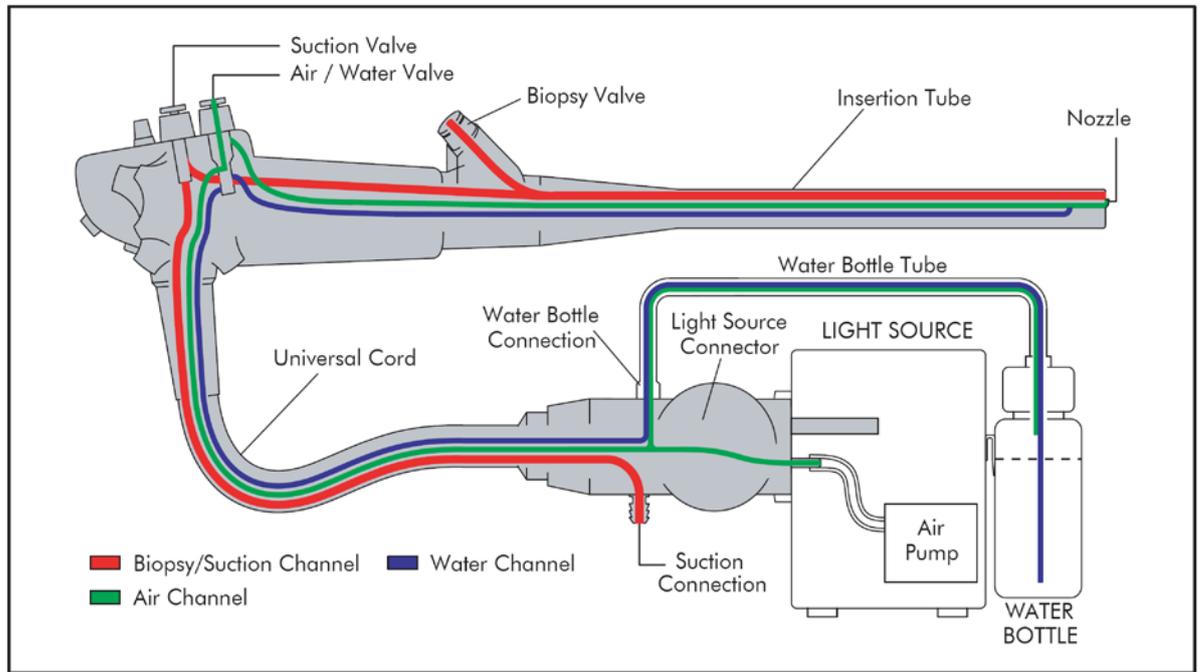
**Table 3: Summary of classification of vCJD risk relevant to GI Endoscopic Practice (Section 4c):**

Type and status of vCJD diagnosis	Management of the endoscope
1. vCJD diagnosis confirmed	Destroy or decontaminate and store in quarantine for use on the same patient
2. Symptoms of CJD but awaiting diagnosis	Decontaminate and store in quarantine. If vCJD confirmed manage as 1. above
3. Asymptomatic patients at increased risk through receipt of labile blood components (whole blood, red cells, white cells or platelets) from a donor who later developed vCJD	Destroy or decontaminate and store in quarantine for use on the same patient
4. At increased risk (e.g. plasma product recipients) For details about the different types of at increased risk classification see the ACDP TSE guidance Part 4 (table 4a) <a href="http://www.dh.gov.uk/health/files/2012/11/Part-4-Infection-Control-Jan13.pdf.pdf">http://www.dh.gov.uk/health/files/2012/11/Part-4-Infection-Control-Jan13.pdf.pdf</a>	Decontaminate and reuse

**Table 4 Total viable count results guide (Willis: ref 43)**

Aerobic colony count in 100ml	Interpretation/action	
0	Satisfactory	
1-9 (achieved on a regular basis)	Acceptable: indicates that bacterial numbers are under a reasonable level of control	
10-100	Unsatisfactory: investigate potential problems and superchlorinate	
>100	Unacceptable: take washer-disinfector out of use until water quality improved	

## STANDARD CHANNELS - AIR, WATER & SUCTION



**Figure 2: Basic design of a gastrointestinal endoscope. More complex designs apply for endoscopic ultrasound scopes (balloon channel) and duodenoscopes (elevator wire).**  
Courtesy Olympus Keymed UK Ltd

## 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. There should be physical separation between dirty and clean areas, with one-way flow of endoscopes, to prevent cross contamination. Best practice is that there should be separation of staff in dirty and clean areas. **D.**
  - 3. During lists and between patients a process of thorough manual cleaning with a low foaming neutral medical grade detergent which is compatible with the endoscope is an essential step before endoscope disinfection. **C.**
  - 4. 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.**
  - 5. The use of automated endoscope washer disinfectors is mandatory; manual disinfection is unacceptable. If the washing cycle is interrupted it will need to be repeated **D.**
  - 6. An effective detergent and disinfectant which is compatible with the endoscope and approved by the endoscope washer disinfectant manufacturer should be used in decontamination. **C.**
  - 7. Units should no longer be using aldehyde-based disinfectants due to their fixative properties and potential for triggering occupational-related disease. **B.**

8. 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**.
9. It is essential that all reprocessing stages are included after every use of the endoscope, and that none are omitted. It is also vital 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**.
10. Endoscopy should be avoided whenever possible in patients with suspected or confirmed vCJD. Where this is considered essential it will be necessary either to discard the endoscope or reprocess it and store for exclusive re-use in the same patient **D**.
11. Quarantining of endoscopes becomes necessary following the performance of invasive endoscopic procedures (including unsheathed biopsy) in patients with or presumed infected by vCJD. Such endoscopes should be decontaminated singly with single-use disinfectant. **D**.
12. Endoscopes decontaminated in accordance with these guidelines can return to use following all forms of endoscopy in the most prevalent at-risk group (plasma product recipients) **D**.
13. "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. **B**.
14. Rubber biopsy port caps must 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**.
15. Health surveillance of staff should include a pre-employment enquiry regarding asthma, skin and mucosal sensitivity problems. Lung function may need to be documented by means of spirometry, especially if there is a history of pre-existing respiratory symptoms or known asthma. 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**.

16. All health care workers involved in endoscopic practice should have been immunised in accordance with local occupational health policy. **B.**
17. Staff carrying out endoscope decontamination should wear gowns and single use gloves which should be changed between each endoscope decontamination session. Eye and face protection is essential. Staff should cover wounds and abrasions. **D.**
18. Safe working practices in the decontamination area of each unit should be written down and understood by all staff. **D.**
19. When transporting endoscopes to and from areas outside the endoscopy unit, they must be transferred in a covered rigid receptacle. For dirty endoscopes the receptacle should be lockable and appropriately labelled as a potential medical hazard. **D.**
20. If an emergency endoscopic procedure is performed out of hours, an assistant with specialist knowledge of endoscopes and their decontamination must be available. **D.**
21. Bacteria-free water should be used in the rinse cycle of automated endoscope reprocessors. It is recommended that the final rinse water from each reprocessor should be confirmed as free of micro-organisms on a weekly basis. **C .**
22. 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 and be aware of potential chemical and biological hazards. **D.**
23. 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.**
24. Disinfectants used in endoscope washer disinfectors must be approved by the EWD manufacturer as compatible with its equipment, and must be used at the correct temperature according to the manufacturer's instructions. **C.**
25. It is recommended that endoscopes are stored in drying or active storage chambers. Where these are used the early morning decontamination cycle may be waived provided that endoscopes have undergone a full reprocessing cycle within the interval for which the cabinet manufacturer can document absence of microbial re-contamination. In some cases this may be for as long as one month. **C.**
26. All detachable components should have been removed at the manual cleaning stage and should not be replaced until the endoscope is next used. **D.**

27. Given the “standard precautions” for endoscope decontamination there is little logic to placing “high risk” patients at the end of procedure lists. Nonetheless local infection control policies may dictate that patients with known *Clostridium difficile* – associated diarrhoea, 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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