



WORKING PARTY REPORT

Decontamination of minimally invasive surgical endoscopes and accessories

Chaired by G. Ayliffe for the Minimal Access Therapy
Decontamination Working Group*

Summary:

- (1) Infections following invasive endoscopy are rare and are usually of endogenous origin. Nevertheless, infections do occur due to inadequate cleaning and disinfection and the use of contaminated rinse water and processing equipment.
- (2) Rigid and flexible operative endoscopes and accessories should be thoroughly cleaned and preferably sterilized using properly validated processes.
- (3) Heat tolerant operative endoscopes and accessories should be sterilized using a vacuum assisted steam sterilizer. Use autoclavable instrument trays or containers to protect equipment during transit and processing. Small bench top sterilizers without vacuum assisted air removal are unsuitable for packaged and lumened devices.
- (4) Heat sensitive rigid and flexible endoscopes and accessories should preferably be sterilized using ethylene oxide, low temperature steam and formaldehyde (rigid only) or gas plasma (if appropriate).
- (5) If there are insufficient instruments or time to sterilize invasive endoscopes, or if no suitable method is available locally, they may be disinfected by immersion in 2% glutaraldehyde or a suitable alternative. An immersion time of at least 10 min should be adopted for glutaraldehyde. This is sufficient to inactivate most vegetative bacteria and viruses including HIV and hepatitis B virus (HBV). Longer contact times of 20 min or more may be necessary if a mycobacterial infection is known or suspected. At least 3 h immersion in glutaraldehyde is required to kill spores.
- (6) Glutaraldehyde is irritant and sensitizing to the skin, eyes and respiratory tract. Measures must be taken to ensure glutaraldehyde is used in a safe manner, i.e., total containment and/or extraction of harmful vapour and the provision of suitable personal protective equipment, i.e., gloves, apron and eye protection if splashing could occur. Health surveillance of staff is recommended and should include a pre-employment enquiry regarding asthma, skin and mucosal sensitivity problems and lung function testing by spirometry.
- (7) Possible alternative disinfectants to glutaraldehyde include peracetic acid (0.2–0.35%), chlorine dioxide (700–1100 ppm) and superoxidized water. These are very effective, killing vegetative bacteria, including mycobacteria, and viruses in 5 min and bacterial spores in 10 min. An endorsement of compatibility with endoscopes, accessories and processing equipment is required from both the solution/device manufacturer and the endoscope manufacturer. Other important considerations are stability, cost and safety from the user and environmental standpoints.
- (8) Cleaning and disinfection or sterilization should be undertaken by trained staff in a dedicated area, e.g., SSD or TSSU. A suitable training programme is described.

Received 9 September 1999; revised manuscript accepted 23 December 1999.

Correspondence to: Mr John Babb, Laboratory Manager, Hospital Infection Research Laboratory, City Hospital NHS Trust, Birmingham, B18 7QH, UK.

*Professor Graham Ayliffe (*Chairman*), Birmingham, UK; Miss Christina Bradley (*Secretary*), Birmingham, UK;

Mr John Babb, (Corresponding author), Birmingham, UK; Mr Mark Jackson, Southend on Sea, UK; Mrs Maureen Johnson, Stockton on Tees, UK; Mr Eric Taylor, Alexandria, UK; Mr John Hansford, Sully, UK; Mrs Ishbel Ingram, Salford, UK; and Mr Chris Fowler (formerly tutor, Minimal Access Therapy Unit, Royal College of Surgeons), London, UK.

- (9) If endoscopes are processed by immersion in disinfectants, harmful residues must be removed by thorough rinsing. Sterile or bacteria free water is essential for rinsing all invasive endoscopes and accessories to prevent recontamination.
- (10) If an automated washer disinfectant is used it must be effective, non-damaging, reliable, easy to use and its performance regularly monitored.
- (11) If used, washer disinfectants and other processing equipment should be disinfected on a regular basis, i.e., between patients or at the start of each session. This will prevent biofilm formation and recontamination of instruments during rinsing. Disinfection should include the water treatment system, if present.
- (12) To comply with the Medical Devices Directive, manufacturers are obliged to provide full details on how to decontaminate the reusable devices they supply. This should include details of compatibility with heat, pressure, moisture, processing chemicals and ultrasonics.
- (13) The Infection Control Team should always be involved in the formulation and implementation of decontamination policies. Wherever possible, the national good practice guidelines produced by the Medical Devices Agency and/or professional societies should be used.
- (14) Single use accessories are often preferred but should only be reused if it is cost effective and safe to do so. The hospital or trust must take corporate legal responsibility for reprocessing and reuse of single use items. Single use items must not be reused if suitable reusable items are available.

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Keywords: Decontamination; surgical endoscopes and accessories; guidelines.

Introduction

The expansion of minimal access surgery over the past 10–15 years and an increase in instrument complexity has highlighted the need for specific guidelines on the cleansing, disinfection and sterilization of rigid and flexible operative endoscopes and their accessories, as well as the introduction of training courses for those undertaking equipment reprocessing.

The safe processing of equipment is mainly concerned with prevention of infection. Infection acquired during operative endoscopy can be endogenous from the patient's own skin flora, or from the internal organs, e.g., gastrointestinal tract, and is the most common. Exogenous infection may be acquired from the air of the operating room or the hands or protective clothing of operating staff. It may also arise from inadequate decontamination of the endoscope or accessories or from contaminated lubricants, dyes, irrigation fluids or water used for rinsing after immersion of the endoscope or accessory in a disinfectant.

Earlier studies showed that infection in laparoscopic surgery from inadequately decontaminated instruments was rare^{1–3} despite exposures to 2% glutaraldehyde for only 10–20 min. Although these processes would not necessarily kill spores, infections caused by spore bearing organisms were not reported. Few spores can be isolated from washed endoscopes.⁴ In one study of over 12 000

arthroscopies, only five patients were infected and these were caused in four cases by *Staphylococcus aureus* and in the other by an anaerobic streptococcus.⁵ In a more recent study of 151 arthroscopies, there were only three infections, probably due to airborne contamination.⁶ The small number of infections in these studies were mainly due to skin flora and not to inadequate instrument decontamination. Non-sporing organisms would have been destroyed by 2% glutaraldehyde in less than 2 min. The shorter length of stay of the patient in hospital and the lesser extent of tissue damage associated with endoscopy should reduce the likelihood of postoperative wound infection. There has been a marked reduction in the incidence of postoperative infection following laparoscopic cholecystectomy^{7–10} but this has not been so easily demonstrated following laparoscopic appendectomy.^{11–15} The evidence would suggest that laparoscopic hernia repair is also accompanied by a lower incidence of infection.^{16,17} Although large prospective studies assessing endoscopy acquired infections have not been made, there is no clinical evidence from more recent studies of infection occurring following high level disinfection procedures instead of sterilization.

Although the transfer of hepatitis B and C, *Mycobacterium tuberculosis*, salmonella, *Pseudomonas aeruginosa* and other Gram-negative bacilli has been reported following gastrointestinal endoscopy or bronchoscopy^{18–20}, none of these have been

reported following minimal access surgery. Despite the rarity of infection, the risks of inadequate processing remain.

Several professional societies have convened groups which have produced guidelines for other types of endoscopes, e.g., gastrointestinal, bronchoscopes and urological.²¹⁻²³ No such advice has been forthcoming from other professional organizations for surgical or invasive instruments, although advice is available from Department of Health guidelines²⁴ and other publications.^{1,25}

The main problem in the decontamination of surgical endoscopes is the inadequate numbers available and the lack of heat-tolerant instruments and accessories. Reprocessing is required during an operation list and low temperature sterilization or immersion in a sporicidal disinfectant, e.g., with ethylene oxide or exposure to glutaraldehyde for 3 h is too slow.

High level disinfection such as exposure to glutaraldehyde for 10–20 min is usually carried out and although there is no evidence of infection problems, sterilization is still preferred.²⁶ Many rigid endoscopes are now heat-tolerant and can be autoclaved, but flexible endoscopes are damaged by temperatures in excess of 60°C, which is below that recommended for thermal disinfection. Heat-tolerant flexible endoscopes are unlikely to be available in the near future. Cameras and associated equipment are often incorporated within the operative endoscopy system and are also heat labile. To avoid the necessity for reprocessing, an increasing number of endoscope accessories are labelled as single use. This may be due to the difficulty of cleaning, probable damage during a single use or a single reprocessing, or it may be cost effective to use the item once and discard.

Survey

In order to establish current decontamination practices for invasive endoscopes and accessories, the working group conducted an anonymous postal survey which was distributed to UK processors through the Infection Control Nurses Association.

Respondents described a large portion (75%) of rigid endoscopes as autoclavable but only 44% were processed by this method. Immersion in 2% glutaraldehyde was the most popular processing option and ethylene oxide was rarely used. Disinfectant contact times ranged between 4 min and 10 h. Endoscopes were initially cleaned manually, but most flexible endoscopes were then re-cleaned and

disinfected using automated systems. Most operators had received training that was often specific. Written decontamination policies were available, but staff rarely kept a record of each decontamination procedure. Single use items were widely used, particularly those most likely to be damaged during subsequent processing. Cost was said not to be a major factor in the selection of single use items.

Most flexible endoscopes were processed in the theatre or endoscopy suite using automated washer disinfectors, most commonly with 2% glutaraldehyde. Heat tolerant accessories were usually returned to a sterile services department (SSD) for autoclaving. Disinfectant contact times recommended by either the disinfectant manufacturers or identified national guidelines were followed by 59% of respondents.

The survey highlighted inadequacies in the UK in identifying the existing appropriate guidance on processing invasive endoscopes and accessories. Additionally, the limited number of available instruments has meant that decontamination is usually carried out in the operating suite, often with inadequately trained staff and suboptimal facilities.

Decontamination of operative endoscopes and accessories

Laparoscopic, urological and arthroscopic telescopes and their accessories are now largely heat-tolerant and can be autoclaved, but some are still heat-labile as are all flexible fiberoptic or video endoscopes. Ethylene oxide is the most appropriate method of sterilization of heat-labile endoscopes and accessories but this method, and the new gas plasma processes, are too slow for use during routine operating sessions, especially where few instruments are available and sessions are busy. Low temperature steam (e.g., at 73–80°C) with formaldehyde is also appropriate^{24,26,27} but is also too slow and rarely used.

The common method of decontamination of operative endoscopes during surgical sessions is immersion in 2% activated alkaline glutaraldehyde for 10–20 min.^{1,24} Most bacteria and viruses, including HIV, hepatitis B virus (HBV) and probably hepatitis C virus, are killed or inactivated in less than 5 min immersion in 2% glutaraldehyde.²⁸⁻³⁵ *Mycobacterium tuberculosis* is more resistant, but is killed in 20 min.³⁶⁻³⁹ However, immersion in disinfectants can be criticized as inadequate because it is a disinfection and not a sterilization process. Items cannot be wrapped to protect them from

re-contamination and equipment requires rinsing in sterile water to remove toxic disinfectant residues. Test spores used to validate sterilization processes, require an exposure time of 3–10 h⁴⁰ in 2% glutaraldehyde. Nevertheless, there is no evidence of infections with spore-bearing organisms occurring following a procedure with a well cleaned rigid endoscope and 10–20 min immersion in glutaraldehyde.^{1,41} Thorough clearing alone will remove most organisms from endoscopes and accessories.^{42,43}

Single-use accessories

Although endoscopes are reprocessed many times, accessories are often labelled single-use. This may be because of difficulty in cleaning or damage during use or subsequent reprocessing. It may also be more cost-effective to use the item once and discard, however, many accessories are expensive and can be reprocessed safely, albeit for a limited number of times.^{44,45} Manufacturers should be encouraged to produce reusable accessories, which are accessible for cleaning and preferably heat stable, if this is cost effective.

Reprocessing of single-use items removes the legal responsibility from the manufacturer and exposes the reprocessor and the user to possible legal action for negligence if a complication due to reprocessing occurs.⁴⁶ However, negligence is more likely to be proven if a single use device is reused, as this is clearly outside of the manufacturers 'intended use'.

For this reason, the cleaning and disinfection or sterilization process for single use items must follow a strict protocol⁴⁷ and may need to specify a maximum number of processing cycles. The process must have been validated by the processing authority to ensure that a safe, effective and acceptable product is produced. It must be remembered that reprocessing may be microbiologically effective but may cause damage or deterioration to the mechanical integrity of a single use device. Records should include details of the processing and the number of episodes of re-use. It is important that the hospital or Trust takes on the responsibility for reprocessing rather than individuals. A device assessment group should be set up to consider the risks of reprocessing to the patient or members of staff involved, the cost-effectiveness of the proposed process, as well as the practicality of the processing methods required. It should report its findings to the Chief Executive (or equivalent), either directly or through the Infection Control Committee, Safety Committee or a relevant directorate.

Principle methods of decontamination

Decontamination

This is a general term used for the removal or destruction of micro-organisms, soil and other unwanted contaminants which may prejudice the safe use of a medical device. It includes cleaning, disinfection and sterilization.

Cleaning

This is a process which removes contaminants, including organic matter (e.g., body fluids and faeces) and most micro-organisms. Cleaning is always required before disinfection or sterilization, especially when processing at low temperatures, as the presence of proteins protect micro-organisms from destruction by chemical agents. Wherever possible, endoscopes require a thorough initial brush followed by washing with a detergent approved by the manufacturer, either by hand or in a machine. An enzymatic detergent and/or ultrasonic cleaner may sometimes be appropriate for cleaning of accessories. Ultrasonic cleaning is unsuitable for telescopes.

Disinfection

This a process which reduces the number of viable micro-organisms present on a surface or medical device to a level previously specified as appropriate for handling or its intended further use. It does not necessarily kill or remove all micro-organisms (particularly spores), but reduces them to a safe level. In laboratory tests, disinfectants should kill at least 10⁵ organisms over a time period similar to that used in practice, usually 10 min or less. Tests which mimic in-use conditions should be carried out before a disinfectant is accepted. Disinfectants should also be compatible with instrument components and processing equipment. Disinfectants all have the disadvantage that recontamination can occur during rinsing to remove toxic residues and instruments cannot be packaged to prevent recontamination during storage. Sterile (autoclaved) or bacteria free (filtered) water is necessary for rinsing. The properties and disadvantages of different agents are shown in Table I.

Glutaraldehyde, e.g., Cidex, Asep, Totacide 28, is highly effective and has been used for many years for the disinfection of endoscopes²⁶ but it is irritant and allergenic.⁴⁸ It should only be used in a well ventilated room, exhaust vented cabinet or an enclosed automated processor.⁴⁹ A 2% activated solution is stable for 14–28 days depending on the product. Activated solutions can be reused, provided

Table 1 Disinfectant options for operative endoscopes.

	Properties	Disadvantages
2% Activated alkaline glutaraldehyde e.g., Cidex, Asep, Totacide 28	<p>Non damaging Sporicidal in > 3h Mycobactericidal in 20–60 min Virucidal, bactericidal in <5 min Relatively inexpensive Activity not adversely affected by organic matter Stable for 14–28 days after activation</p>	<p>Sensitizing, irritant to skin eyes and respiratory tract Environmental controls expensive Slow in action against bacterial spores and mycobacteria A fixative, thorough cleaning is essential</p>
0.35% Peracetic Acid used at room temperature e.g., Nu-Cidex* 0.2% peracetic acid used at 45°C e.g., Steris ⁺	<p>Sporicidal in 10 mins* Mycobactericidal, virucidal, bactericidal in <5 min*+ Activity not adversely affected by organic material*+ Single use dose of disinfectant so no dilution within the machine+ Dedicated enclosed processing facility+</p>	<p>Damages copper alloys*+ Expensive*+ Irritant to skin, eyes and respiratory tract*+ Unstable*+ Strong odour of acetic acid – ventilation may be required* Endorsement of compatibility with instruments*+ and processors* is required Has to be used within a dedicated machine which does not include cleaning as part of a cycle+</p>
Chlorine Dioxide 700–1 100 ppm av Cl e.g., Tristel (Lower concentrations under investigation)	<p>Sporicidal in 10 min Mycobactericidal, virucidal, bactericidal in <5 min</p>	<p>Irritant to skin, eyes and respiratory tract Strong odour of chlorine – ventilation is required Damaging, endorsement of compatibility with instruments and processors is required.</p>
Superoxidized Water e.g., Sterilox	<p>Sporicidal in 10 min Mycobactericidal, virucidal, bactericidal in <5 min Solution used once and discarded Solution generated at point of use</p>	<p>Unstable Adversely affected by organic matter Apparatus for generation expensive to purchase/lease Damaging, endorsement of compatibility with instruments and processors is required</p>

* and ⁺, associations between properties/disadvantages of disinfectants listed, i.e., Nu-Cidex*, Steris⁺.

the concentration does not drop below 1.5%.⁵⁰ This should be checked regularly. A less irritant alternative is sought, but glutaraldehyde has one major advantage in that it does not damage instrument or processor components. Any proposed alternative should be as effective, user friendly and approved by the endoscope or instrument manufacturer.⁵¹

Alcohol (ethanol (IMS) and isopropanol) at 60–70% is sometimes used for the disinfection of endoscopes, but an exposure time in excess of 5 min may damage lens cements. Alcohol rapidly destroys most non-spore-forming bacteria, including mycobacteria, but is less effective against enteroviruses.³⁰ Alcohol is flammable and is not therefore recommended for use in automated processors where large volumes are used. Alcohol may be useful for the disinfection of external surfaces of the camera and fiberoptic cables as it evaporates rapidly without leaving residues and subsequent rinsing is unnecessary.

Peracetic acid (e.g., Steris 0.2% used at 45°C or Nu-Cidex 0.35% used at room temperature) has the advantage of being much more rapidly effective than glutaraldehyde, i.e., sporicidal in 10 min and effective against non-spore-forming bacteria including *Mycobacterium tuberculosis*^{37–39} and viruses in less than 5 min. However, in-use solutions are unstable and the disinfectants and processing equipment are expensive. Corrosion of certain metals can occur unless a suitable inhibitor is included. The diluted solution appears to be less irritant than glutaraldehyde, although the vinegary smell is unpleasant. It is the most promising alternative to glutaraldehyde at present but its adoption as a glutaraldehyde replacement is still under investigation.^{21,51}

Chlorine dioxide (e.g., Tristel 700–1100 ppm av Cl). This is also rapidly sporicidal (e.g., 10 min) and is active against non-spore-forming bacteria, including mycobacteria and viruses, in less than 5 min. It is potentially corrosive but commercial preparations contain an inhibitor. It is another possible alternative to glutaraldehyde, if approved by the instrument and processor manufacturers.^{21,51} It is also listed as a respiratory irritant and lower less problematic concentrations have now been introduced.

Superoxidized water (e.g., Sterilox) is the product of the electrolysis of an aqueous saturated salt (NaCl) solution passed over proprietary catalysts to give a mixture of oxidizing species, particularly OCl^- . It is highly microbicidal when freshly generated provided items are thoroughly clean and strict generation criteria are met, i.e., current, pH and redox potential (>950 mV).^{52,53} It seems to be safe

for users and provided field trials substantiate laboratory efficacy tests, and the agent is non-damaging, it too may become an alternative to glutaraldehyde.

Sterilization

This is a process which renders an object free of all viable micro-organisms including spores. Prions (infectious proteins), the probable causative agents of Creutzfeldt Jakob disease, scrapie and BSE, are the only relevant exceptions and are resistant to the usual sterilizing processes. For decontamination of possible prion contaminated instruments see Advisory Committee on Dangerous Pathogens guidelines.⁵⁴

Autoclaving is the preferred option for the routine sterilization of heat tolerant medical devices. The newer generation of rigid endoscopes, including the telescope and hand instruments, are autoclavable. Before steam sterilization, confirm compatibility with the endoscope manufacturers. Lumened and/or packaged instruments should be processed using a porous load or vacuum assisted autoclave.^{27,55,56}

Ethylene oxide (EO) is a reliable process provided it is well controlled and validated. It requires special environmental controls and is only available in a limited number of sterile service departments. As the gas is toxic, potentially explosive and is absorbed by some plastics and rubbers, items must be aerated to elute toxic residues before they are reused. Sterilization may take up to 6 h and subsequent spore validation and aeration may increase delays before reuse to one week.

Low temperature steam with formaldehyde (LTSF) at 73°C is suitable for sterilizing rigid endoscopes that will not withstand autoclaving but will tolerate 80°C. Items should be thoroughly cleaned, dried and packaged as for porous load autoclaving. The cycle is lengthy (3 h), the process complex and, because biological indicators are required for validation these can delay release of the processed items for a week or more. As with ethylene oxide, very few hospitals have LTSF processing facilities.

Gas plasma (e.g., Sterrad) is a recently introduced low temperature (45°C) method of sterilization whereby a highly reactive plasma is created by passing radio waves through vaporized hydrogen peroxide. It is expensive, but no toxic residues remain at the end of process and the cycle time is shorter than EO. However, it is unsuitable for moist and lengthy narrow lumened devices. Its suitability for flexible endoscopes is still being investigated.^{57,58}

Table II Sterilization and disinfection of operative endoscopes and accessories.

STERILIZATION	
Heat tolerant items	
Autoclaving	121°C for 15 min
(Vacuum assisted air removal)	134°C for 3 min
Heat sensitive items	
Ethylene oxide	37–55°C up to 6 h
Low temperature steam and formaldehyde*	73–80°C up 3 h
Gas plasma†	45°C for 50 or 72 min
DISINFECTION	
Heat tolerant items	
Subatmospheric steam	73–80°C for 10 min
Washer disinfectant/pasteurizer (BS 2745)	71°C for 3 min 80°C for 1 min 90°C for 12 sec
Heat sensitive items	
Sporicidal disinfectants	
2% glutaraldehyde	> 3 h
0.2–0.35% peracetic acid	10 min
700–1100 ppm chlorine dioxide	10 min
High level disinfection	
2% glutaraldehyde	10 min‡
0.35% peracetic acid	5 min
700–1100 ppm chlorine dioxide	5 min

*unsuitable for flexible operative endoscopes;

†suitable for rigid endoscopes, suitability for all flexible endoscopes yet to be established;

‡longer contact times, i.e., >20 min may be required if mycobacterial infection is known or suspected.

For a more comprehensive review of process options consult the Guidance on Decontamination from the Microbiology Advisory Committee to the Department of Health Medical Devices Agency Parts 1 and 2 (Principles and Protocols).

Further information on process parameters may be found in Table II.

Choice of decontamination method

Steam sterilization is the preferred option for all heat-tolerant invasive endoscopes and accessories. However, some rigid and all flexible endoscopes are heat labile. Ethylene oxide or possibly low temperature steam and formaldehyde (rigid endoscopes) and gas plasma are the preferred options for sterilization but these methods are usually impractical due to time restraints, lack of instruments and suitable processing equipment. Disinfectants are therefore the only practical means of disinfection. Although this method is not optimal there is no evidence of infection due to inadequate

decontamination following immersion in 2% glutaraldehyde or an alternative for 10 min.

The selection of a suitable disinfectant is dependant on its efficacy, compatibility with instruments and processing equipment, user and patient safety and cost. No disinfectant meets all the selection criteria. Before changing an instrument disinfectant or process, it is therefore important to seek the advice of the infection control team, instrument and processor manufacturers. The use of an incompatible agent or process may invalidate guarantees and service agreements. Endoscopes, accessories and processors are medical devices and manufacturers must provide information on suitable process options, i.e., tolerance to heat, pressure, moisture and processing chemicals. Also the change must be carefully costed bearing in mind the use life of the disinfectant and the provision of exhaust ventilation or personal protective equipment to meet the COSHH requirements. It is important to notify those responsible for formulating policies, i.e., the professional societies or the Medical Devices Agency of progress be it favourable or not.^{24,51}

Automated chemical washer disinfectors for minimally invasive equipment

Automated chemical washer disinfectors which clean, disinfect and rinse external surfaces and lumens are widely available for flexible endoscopes^{49,59} but machines that irrigate the lumens of rigid endoscopes are not so common.⁶⁰ However, fume cupboards and systems that protect staff from skin and vapour contact with processing chemicals contained in tanks and trays are widely used. As many rigid endoscopes are now autoclavable, the use of chemicals in washer disinfectors is discouraged in favour of cleaning and steam sterilization in the SSD.²⁴

Endoscopes which are invasive, e.g., arthroscopes, laparoscopes, or enter sterile body cavities, e.g., cystoscopes, should be rinsed with sterile (autoclaved) or bacteria-free water. Machines for processing these endoscopes may be fitted with bacteria retaining filters which have a pore size of 0.22 µm. A maintenance schedule should be in place for the replacement and decontamination of these filters, their housings and associated tubing, otherwise biofilm formation and bacterial contamination is likely.

To avoid the risk of recontaminating endoscopes with machine associated micro-organisms, e.g., atypical mycobacteria and *Pseudomonas* spp., a self disinfection procedure should be performed prior to

starting a days list. This should also include the water filtration system. Washer disinfectors used for processing endoscopes and accessories should be properly validated and include an automated self disinfect cycle. This should include the filtration and all rinse water pathways.⁶¹

Ultrasonic cleaning below protein coagulation temperatures is highly effective on external surfaces but is damaging to some telescopes and is unlikely to be effective on internal lumens. If ultrasonics are used, component compatibility should be checked with the manufacturers and all lumens flushed during or after cleaning.

The detergents and rinse water used in machines should be changed frequently, preferably after each cycle, to prevent re-soiling and the build-up of irritant chemical residues. The disinfectant should also be changed frequently as the carry over of detergent/rinse water reduces the potency. Guidance should be sought from the washer disinfectant manufacturer on exchange frequency. Some disinfectant manufacturers produce test kits which give an indication of dilution during processing.

Automated chemical washer disinfectors for the decontamination of minimally invasive equipment should only be used if they do not recontaminate processed items, and irritant vapours are contained or removed. Also the water used for rinsing must be free of micro-organisms and bacterial endotoxins if recontamination of processed endoscopes is to be avoided.⁶¹

Processing of equipment for minimal access therapy

The range of equipment is extensive and increases as new instrument designs and operative procedures are introduced. Instrumentation includes endoscopes (rigid and flexible), hand instruments, accessories (scissors, forceps, snares etc.) receptacles, tubing, brushes and needles. All are defined as 'medical devices' and come under the scope of the Medical Devices Directive 93/42/EEC. Their intended use may be described as single use or reprocessable.

Single-use items

These will be marked with the 'do not reuse' symbol and/or labelled by manufacturers as 'intended for single-use'. Such devices should not be reused

unless the consequences have been considered and the hospital has a documented and validated procedure for doing so.^{46,47}

Reprocessable items

Some devices have a limited life. This will depend on their durability during handling, processing and subsequent reuse. Others, such as surgical instruments, are made to withstand repeated reprocessing. Manufacturers should issue guidance on the appropriate reprocessing methods to be used, i.e., tolerance to moisture, heat, pressure, chemicals etc. and the criteria for reuse. This advice must be followed.

Reprocessing: premises and facilities

It must be noted that hospitals and clinics which reprocess devices (reusable or single use) and provide them to other institutions, either free of charge or at a price, become 'manufacturers' under the Medical Devices Directive and must therefore be able to demonstrate the reprocessed devices fulfil all relevant 'essential requirements' of the Directive. Most reprocessing will either take place in the operating suite or SSD at the hospital in which the instrument is used. Although it is not necessary to meet the requirements of the Directive in every case, it is advisable that a recognized quality system is used. The following points should be considered when setting up a reprocessing facility for minimal access instrumentation either in an operating suite or SSD:

- (1) the workload and the range of decontamination procedures being (or to be) undertaken;
- (2) the availability of skilled staff with management/line responsibility;
- (3) the range and availability of suitable processing equipment;
- (4) the hospital policy for sterilization and disinfection, which should include any service level agreements and contractual arrangements.

The choice of processing establishment will depend on location and workload. The decontamination area should be designed to encourage a progressive workflow from the receipt of dirty used instruments to the release of those which are clean, disinfected or sterile ready for reuse.⁶²⁻⁶⁴ Spot lighting and magnification will be required for inspection

and function testing at selected work stations. Some items will require testing or drying using filtered compressed air. Storage space/accommodation in the work area should be sufficient for sessional processing requirements. The working area should be cleaned regularly to a specified standard.

Staff

Staff engaged in any part of the reprocessing cycle should be trained for their role and aware of all relevant health and safety requirements. On site supervision is advised. A record should be kept of all training given, and levels of competence achieved.

Suitable protective clothing should be provided for processing staff, i.e., gloves (nitrile if glutaraldehyde is used) and fluid resistant gowns or aprons. Visors or goggles should be worn when decanting processing chemicals, jet washing lumened devices or any other procedure where splashing could occur.

Pre-employment health checks should be followed by routine 'in service' surveillance. All accidents involving personal injury and evidence of skin reactions and respiratory problems, must be reported and documented by the Occupational Health Department. Many of the chemicals used for processing endoscopes and accessories are irritant to the skin, mucosa and respiratory tract.⁴⁸ Vaccination against tetanus and hepatitis B virus is advised.

Operating procedures

Detailed written 'standard operating procedures' should be prepared for the activity in each area. This should form the basis of the staff training programme. The quality system should be reviewed periodically and following internal and external auditing by a competent authority.

All machine performance checks, plant history records and daily process logs must be retained for inspection. All machines must be regularly maintained and subjected to a preventative maintenance schedule. Malfunction or untoward incidents and personal accidents should be reported to the line manager without delay. The performance of the washer disinfectors and sterilizers should comply with the good practice guidelines described in HTM 2010⁵⁵ and HTM 2030.⁶¹

Transport of equipment after patient use

Used equipment may be contaminated with potential pathogens. Staff should understand this risk

and take reasonable precautions. They should be familiar with the local policy for dealing with 'biohazards'.

Users are responsible for checking that all used instruments and accessories are present, that single-use devices, including sharps, have been safely disposed of and that re-usable sharps are suitably protected. Fluid reservoirs should be emptied and gross soiling removed in the users department. If a delay is anticipated before processing, it is recommended that lumens are flushed with water or detergent and external surfaces are wiped clean. This will prevent blood and other body fluids drying on the surfaces making subsequent removal difficult.

The preferred method of protecting staff and equipment during transfer to a separate reprocessing area is by 'containment', i.e., wrapping equipment or placing it in a container. Draping material, packaging and delivery trays may be used to protect used items during transit. If the journey to the reprocessing area is difficult or outside, closed trolleys should be used.

Decontamination

This consists of cleaning followed by disinfection and/or sterilization. Returned items are checked off against the list before being grouped for decontamination. If all items in a set cannot be processed by the same method, a marking or tagging system must be used to keep track of components. The preferred initial method is thermal disinfection using an automated washer/disinfector designed and operated in accordance with the recommendations in BS 2745⁶⁵ and HTM 2030.⁶¹ Heat sensitive micro-surgical instruments and some lumened devices may require manual cleaning and jet washing in open sinks. This is less efficient, does not disinfect and exposes staff to greater infection risks from splashing and aerosols. Automated chemical washer disinfectors are appropriate for heat labile endoscopes but few machines are available at present for processing heat sensitive rigid endoscopes. Contaminated items including hand instruments, needles, tubing and some lumened devices may be processed in a bench top ultrasonic cleaner, preferably with a rinse system for irrigating lumens. After cleaning, the final rinse should be in endotoxin free water.⁶¹

Inspection and function testing

All items or components should be checked prior to assembly, packaging, disinfection, sterilization or

despatch. Any incomplete, soiled or defective items should be reported and investigated. Precise criteria for acceptance or rejection will be agreed locally, but no instrument showing signs of damage, excessive wear or malfunction should be passed on for assembly or further processing. Rejected items must be isolated, replaced and/or repaired. Manufacturers should be able to advise on acceptance or rejection criteria. Specified components should be lubricated in accordance with the manufacturer's instructions.

Assembly and packaging

Equipment to be sterilized by physical processes can be assembled in 'ready to use' condition and presented as:

- (1) *Single items*, e.g., endoscopes or specific instruments not required for every procedure.
- (2) *Sets of instruments* arranged on flat bed trays or in boxes using heat stable foam or spiked sheets of heat resistant rubber to hold and protect delicate items in a pre-determined sequence, or in dedicated trays where instrument position is indicated by pre-formed outlines. Trays may include accessories such as tubing, adapters, brushes and holloware. The inclusion of drapes and dressings will prevent the movement of contents but may, unless wrapped, release particles which compromise the efficiency of some instruments. Packaging material should facilitate air removal and penetration of the sterilant.

The contents must comply exactly with the check list to be included in the pack or tray. The arrangement of the instruments within the set will be agreed with the user. Often instruments are placed in order of use but the arrangement must not inhibit the circulation of the sterilant. On the occasions when it is necessary to place one item above another, separation by a layer of porous material is essential to prevent movement which may cause damage. The use of approved materials and closure methods appropriate to the sterilization process will prolong the shelf life after the terminal process. When devising new pack or tray layouts, or changing the contents or packaging materials, the proposed method should be tested in preliminary trials to ensure complete penetration of the sterilant. All items must be clearly labelled indicating the contents, processor, production/sterilization date and sterilization process indicators.

Sterilization or disinfection

The process options are previously described. All items should preferably be autoclaved.^{27,55} A bench top autoclave may be suitable if sterilization is carried out in the operating suite but the process should be monitored and the machine maintained as in the SSD.⁵⁶ A vacuum assisted (porous load) sterilizer is preferred for porous loads, packaged and lumened devices.⁶⁶

Distribution and storage

Those responsible for transporting minimal access therapy instruments must recognize the delicate and expensive nature of the equipment. Each item or container must be labelled with its destination. Packs and trays should always be held horizontally and never transported by hand over long distances. Suitably sprung and shelved trolleys may be used for internal distribution preferably enclosed to give added protection and security.

Suitably packaged contained items will have a long 'shelf life' provided the storage facilities are dry, well ventilated, vermin proof, clean and the stock is not subjected to direct sunlight. Stock should be stored in a designated location familiar to all legitimate users. Newly arrived stock should be placed behind older stock to ensure correct rotation.

Health and safety

In addition to the general range of health and safety requirements, the following have particular relevance to reprocessing minimally invasive endoscopes and accessories:

- (1) The Control of Substances Hazardous to Health Regulations⁶⁷ for the storage and use of detergents, disinfectants lubricants and other processing chemicals.^{48,64}
- (2) Occupational exposure limits for aldehydes, ethylene oxide and formaldehyde (EH 40/99).⁶⁸
- (3) All accidents and untoward incidents must be reported using a locally agreed procedure.

Risk assessment and policy formulation

Infection control practitioners (e.g., infection control doctor and nurse) and risk managers will be included in a multi-disciplinary group (e.g., Infection Control Committee) that formulates, publishes and revises policies that affect the operation of the service. Wherever possible they will include or implement national good practice guidelines produced by the

Department of Health, e.g., DB 9607²⁴ or professional societies. Procedures will cover procurement advice, between patient decontamination, procedures for dealing with known infections and 'biohazards', the 'decontamination of medical equipment prior to maintenance, repair and servicing' and 'single-use'.

Documentation and quality assurance

The unit will have, or be, working towards compliance with a recognized Quality System Standard.⁶³ Mission statements and hospital policy will be complemented by documented 'standard operating procedures'. In addition to these there will be established procedures for:

- (1) notifying complaints, defects etc: this should lead to system or procedural reviews;
- (2) liaison with the users to introduce improvements;
- (3) assessing the level of user satisfaction.

The quality system should ensure product traceability, the source of raw materials, suppliers, method and date of processing and the ultimate use which is recorded in the patient notes. A product labelling and/or tracking system is required to achieve this objective. Changes in practice and the introduction of new methods will be recorded and the 'standard operating procedures' updated. All cleaning, disinfection and sterilization processes will be monitored and validated in accordance with national good practice guidelines and records retained by the head of the department, microbiologist or engineer as appropriate. Items sent for maintenance, service or repair must be accompanied by the 'declaration of contamination status' form and signed by the last user or the manager responsible for decontamination. Users are responsible for notifying them that an item requires reprocessing. This it does in the form of a 'permit to work'. Other sections of the same form will be completed by those responsible for decontamination, repairs and maintenance.²⁷ All procedures will be subject to internal and external audit at frequencies determined by the Quality System standard.

Training

The reprocessing of minimal access therapy equipment involves several disciplines, i.e., the user,

processor, infection control practitioner, manufacturer and risk assessor working together to ensure:

- (1) the optimum therapeutic and diagnostic benefit for the patient;
- (2) that policies and procedures are in place which eliminate or minimize infection and other risks e.g., the presence of irritant chemical residues;
- (3) the equipment is maintained in good working order and its use life is prolonged.

These objectives can only be realized if there is a written policy for reprocessing and that, at each stage, there is compliance with it. Local circumstances and the availability of suitable processing facilities will affect the selection of the procedures used. These will form the basis of a co-ordinated training programme for each member of the team. Training may be given 'in house' or externally. Specialist training is provided nationally by the English National Board (Nursing), instrument manufacturers and professional societies, e.g., the Institute of Sterile Services Management, National Association of Theatre Nurses, Endoscopy Associates Group of the British Society of Gastroenterology and the Infection Control Nurses Association.

Management

Those responsible for managing the training programme should be aware of:

- (1) the chain of responsibility/accountability of those involved in providing the service;
- (2) the essential elements of the reprocessing cycle and the turn around time for individual and grouped items in use;
- (3) their personal responsibility for infection control, safety and quality assurance procedures;
- (4) the advantages of programming the elective use of some very expensive items of equipment;
- (5) procedures for the decontamination of equipment prior to service, maintenance or repair;
- (6) local policies for; risk management, the selection and use of 'single use' items, the disposal of waste, spillage, dealing with contamination caused by exotic pathogens, e.g., prions;
- (7) the procedure for acquiring additional equipment, organizing trials, the commissioning and the validation and registration of new items of equipment;
- (8) devising and revising procedures for reprocessing and the introduction of new processing technologies.

Processors

It is suggested that the following topics should be included in induction training programmes for newly appointed processors, i.e., nurses, operating department assistants and technicians. Selected topics from the list can be incorporated in revision or updating courses and may serve as a checklist for skills assessment.

Training checklist

General

- (1) Quality standards and good practice guidelines, e.g., GMP, Device Bulletins – DB 9607, Health Technical Memoranda 2010, Health Technical Memoranda 2030, British (BS) and European (EN) standards, standard operating procedures;
- (2) The processing environment, i.e., production areas including instrument receipt, disassembly, decontamination, packaging, terminal processing and storage, optimum environmental conditions, good housekeeping, stock control and the provision and storage of raw materials;
- (3) Health and Safety at Work Act to include COSHH, manual lifting, staff health surveillance, protective clothing, first aid, reporting accidents and dangerous occurrences.

Equipment

Properties of materials, design and construction of:

- (1) endoscopes – (rigid and flexible), telescopes, optical systems, including angles of vision, light sources and transmission;
- (2) accessories for making incisions, dissection, haemostasis, cutting, clamping, diathermy, biopsy, irrigation and inflation;
- (3) surgical instruments including those for microsurgery, specialized forceps, lasers, box, screw and compound joints and electrical/electronic components;
- (4) adhesives used in the construction of devices;
- (5) component tolerance to variations in temperature, pressure (positive and negative) and chemicals, e.g., detergents, disinfectants, wetting agents, lubricants, etc.;
- (6) the selection of suitable cleaning, disinfection or sterilization processes complying with the manufacturer's recommendations;
- (7) repair and replacement and reordering procedures.

Materials used in processing

Specification, selection and storage of raw materials:

- (1) containers;
- (2) wrapping materials for composite and single items;
- (3) detergents, lubricants and solvents;
- (4) disinfectants and sterilants.

Presterilized single use items

These include:

- (1) specification and selection of sterile items intended for single use;
- (2) storage conditions, stock rotation and assessing stock levels.

Transportation and distribution

This includes:

- (1) return of items for decontamination after patient use, staff protection and infection control;
- (2) product protection during storage;
- (3) issue of sterile processed items to users.

Organization and procedures in work areas

This includes:

- (1) receipt of used potentially contaminated or hazardous items;
- (2) selecting suitable methods of decontamination, accessibility for manual or automated cleaning;
- (3) physical methods; tolerance to heat, pressure, automated processors and ultrasonics;
- (4) chemical methods; tolerance to chemicals, risks to personnel, importance of removing toxic residues;
- (5) inspection: check that all components of the instrument or set are present, clean and dry;
- (6) function testing: sharpness, correct apposition, grip, insulation, conductivity etc.;
- (7) assembly: single items or sets, protecting delicate, sharp or pointed devices from damage, adding drapes, dressings, sundries and process integrators;
- (8) packaging: in boxes, containers or flexible materials such as paper, pouches, non-woven materials;
- (9) wrapping and closure techniques;
- (10) labels to identify: contents, date of processing, destination of items, processor and process indicators;
- (11) record of process.

Terminal process

Process options, procedures and documentation:

- (1) sterilization process options, i.e., steam (porous load downward displacement), ethylene oxide, low temperature steam and formaldehyde and gas plasma;
- (2) disinfection process options, i.e., low temperature steam, thermal and chemical washer disinfectors or immersion in disinfectants;
- (3) cycle stages, monitoring, e.g., time, temperature, pressure, humidity and gas concentration;
- (4) environmental controls for hazardous chemicals, e.g., ethylene oxide, formaldehyde and glutaraldehyde;
- (5) load acceptance criteria, packaging, inspection, load documentation, processor maintenance log, plant history and records;
- (6) loading and unloading.

Acknowledgement

The Working Group would like to thank the following societies and organizations for their representation and support in preparing the report; the Hospital Infection Society, the Royal College of Surgeons, the Institute of Sterile Services Management, the Infection Control Nurses Association and Keymed Medical and Industrial Ltd.

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