Cleaning and Disinfection of Equipment for Gastrointestinal Endoscopy

Endoscopy Committee

Summary

1. Two percent glutaraldehyde is the most commonly used disinfectant in endoscopy units within the UK. Unfortunately adverse reactions to glutaraldehyde are common amongst endoscopy personnel and the Health and Safety Commission have recommended substantial reductions in atmospheric levels of glutaraldehyde in order to comply with the Control of Substances Hazardous to Health Regulations, 1994. The Working Party addressed ways of eliminating or minimising glutaraldehyde exposure in endoscopy units by reviewing alternative disinfectants and the use of automated washer disinfectors.

2. Peracetic acid is a highly effective disinfectant and may prove to be a suitable alternative to glutaraldehyde. Peracetic acid has a vinegary-like odour and is claimed to be less irritant than glutaraldehyde. Experience with this agent remains relatively limited and the Working Party recommends that peracetic acid should be used in sealed or exhaust ventilated facilities until further experience is obtained. It is considerably more expensive than glutaraldehyde, is less stable and large volumes have to be stored. It causes cosmetic (but not functional) damage to endoscopes and is not compatible with some washer/disinfector machines.

3. Chlorine dioxide is a powerful oxidising agent and highly effective as a disinfectant. Once activated it must be stored in sealed containers with little head space. Fumes are irritant and sealed or exhaust ventilated facilities are necessary. The agent may damage some metallic and polymer components of endoscopes and automated washer/disinfector machines and compatibility should be established with equipment manufacturers before the agent is used.

4. Other disinfectants such as peroxygen compounds and quaternary ammonium derivatives are less suitable because of unsatisfactory mycobactericidal and/or virucidal activity, or incompatibility with endoscopes and automated washer/disinfector machines. Alcohol is effective but, on prolonged contact, is damaging to lens cements. It is also flammable and therefore unsuitable for use in large quantities in automated systems.

5. Superoxidised water (Sterilox) is an electrochemical solution (anolyte) containing a mixture of radicals with strong oxidising properties. It is highly microbicidal when freshly generated, provided items are thoroughly clean and strict generation criteria are met i.e. current pH, redox potential. It appears 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.

6. When 2% glutaraldehyde is used for manual and automated disinfection, a 10 minute immersion time is recommended for endoscopes before the session and between patients. This will destroy vegetative bacteria and viruses (including HBV and HIV). A 5 minute contact period is recommended for 0.35% peracetic acid and for chlorine dioxide (1,100ppm av ClO2), but if a 10 minute period is employed sporicidal activity will also be achieved. At the end of each session 20 minutes immersion in glutaraldehyde or 5 minutes in peracetic acid or chlorine dioxide is recommended.

7. Microbiological studies show that 20 minutes of exposure to 2% glutaraldehyde destroys most organisms, including Mycobacterium tuberculosis. The Working Party concludes therefore that 20 minute endoscope immersion in 2% glutaraldehyde is sufficient for endoscopy involving patients with AIDS and other immunodeficiency states or pulmonary tuberculosis. Similarly, 20 minutes immersion time is recommended at the start of the list and between cases for ERCP when high level disinfection is required.

8. Cleaning and disinfection of endoscopes should be undertaken by trained staff in a dedicated room. Thorough cleaning with detergent remains the most important and first step in the process.

9. Automated washer/disinfectors have become an essential part of the Endoscopy Unit. Machines must be reliable, effective, easy to use and should prevent atmospheric pollution by the disinfectant if an irritant agent is used. Troughs of disinfectant should not be used unless containment or exhaust ventilated facilities are provided.

10. A detailed cleaning and disinfection regime is preferred and this is described.

11. Whenever possible 'single use' or autoclavable accessories should be used. The risk of transfer of infection from inadequately decontaminated reusable items must be weighed against the cost. Re-using accessories labelled for single use will transfer legal liability for the safe performance of the product from the manufacturer to the user or his/her employers and should be avoided unless Department of Health criteria are met. Manufacturers are encouraged to produce more reusable items which are readily accessible for cleaning and are autoclavable.

12. Health surveillance of staff is mandatory and should include a pre-employment enquiry regarding asthma, skin and mucosal sensitivity problems and lung function by spirometry. Occupational health records must be retained for 30 years.

13. Those involved in endoscopic practice should be vaccinated against hepatitis B, should wear gloves and appropriate protective clothing, and should cover wounds and abrasions.
14. Increased funding is necessary for capital purchases of endoscopic equipment, including more endoscopes, washer/disinfectors, exhaust ventilation equipment and single use accessories.

**Members of the working party**

Dr R E Cowan (Chairman)  
Dept of Gastroenterology  
Colchester General Hospital  
Turner Road  
Colchester,  
Essex CO4 5JL

Professor G A J Ayliffe  
Mr J R Babb  
Miss C R Bradley  
Hospital Infection Research Laboratory  
City Hospital NHS Trust  
Dudley Road  
Birmingham B18 7QH

Dr S M Chivers  
Health Services National Interest Group  
Health & Safety Executive  
14 Cardiff Road  
Luton,  
Beds LU1 1PP

Dr J Holton  
Dept of Medical Microbiology  
UCL Medical School  
46 Cleveland Street  
London W1

Mr S M Greengrass  
Keymed (Medical & Industrial Equipment) Ltd  
Keymed House  
Stock Road  
Southend-on-Sea,  
Essex SS2 5QH

Mrs F L Mason  
Beynon Centre  
New Cross Hospital  
Wednesfield  
Wolverhampton  
WV10 0QP
Introduction

In 1988 a British Society of Gastroenterology (BSG) Working Party published recommendations for cleaning and disinfection of equipment for gastrointestinal flexible endoscopy (1). The conclusions of the Working Party were published in the form of good practice guidance which gastrointestinal endoscopy units have used since then. Aldehyde preparations (2% activated glutaraldehyde and related products) were recommended as first line antibacterial and antiviral disinfectants and a 4 minute immersion or contact time was recommended as sufficient for inactivation of vegetative bacteria and viruses (including HIV and HBV).

Following changes in safety legislation and an increase in irritancy and sensitisation to aldehyde disinfectants amongst health care personnel, modifications to these recommendations were required. A second Working Party was convened and, in 1993, a special report was published on 'Aldehyde disinfectants and health in Endoscopy Units'(2). This gave advice on the safe use of glutaraldehyde and similar aldehyde-containing disinfectants.

An extensive review of infections following upper and lower flexible gastrointestinal endoscopy and bronchoscopy was published by Spach et al in 1993 (3).

In December 1994 a third Working Party was convened by the BSG to determine how the 1988 recommendations should be modified. This Working Party has concluded that most of the recommendations of the previous report have stood the test of time. In the UK there have been no reports of transmission of infection resulting from inadequate decontamination of GI endoscopes by those following the 1988 recommendations. Most countries, and the disinfectant manufacturers,
now recommend 10 minutes or longer immersion in 2% glutaraldehyde for routine endoscopy. This improves the margin of safety.

A recent Device Bulletin DB 9607 from the Medical Devices Agency of the Department of Health on the Decontamination of Endoscopes advises that the user of the disinfectant adopts the disinfectant manufacturers’ contact/immersion times (4). These must be supported by experimental studies which demonstrate proven efficacy against microorganisms of significance in terms of their resistance and their association with a particular endoscopic procedure. Leading 2% glutaraldehyde manufacturers recommend a 10 minute contact time for vegetative pathogens including Ps. aeruginosa and viruses such as HIV and HBV.

In response to this, the Working Party has addressed two aspects relating to cleaning and disinfection.

i. **Disinfectant selection** 2% glutaraldehyde is the most widely used agent. It is an effective disinfectant, relatively inexpensive and non damaging to endoscopes, accessories and automated processing equipment but, health and safety issues are a source of considerable concern. It is likely that the legal occupational exposure level for glutaraldehyde will be reduced substantially within the next few years. This will make it more difficult and expensive to adhere to the Health and Safety at Work Act 1974 and thereby comply with the Control of Substances Hazardous to Health Regulations introduced in 1988 and revised in 1994. Accordingly the Working Party reviewed the current status of glutaraldehyde in endoscopic practice and assessed alternative disinfectants.

ii. **Endoscope cleaning and disinfection** Non-immersible endoscopes have virtually disappeared from clinical practice in the UK and the majority of gastrointestinal endoscopy units use automated washer/disinfector machines. The Working Party examined and attempted to define optimal endoscope cleaning and disinfection procedures with particular reference to the use of these machines.

**Disinfectants**

The Working Party reviewed the following agents :-

i. 2% glutaraldehyde (eg 'Cidex', 'Asep', 'Totacide 28')
ii. Peracetic acid (eg 'Nu-Cidex' and 'Steris')
iii. Peroxygen compounds (eg 'Virkon')
iv. Chlorine dioxide (eg 'Tristel', 'Dexit', 'Medicide')
v. Quaternary ammonium compounds (eg 'Sactimed Sinald', 'Dettol ED')
vi. Alcohols (eg Ethanol, Isopropanol, Industrial Methylated Spirits)
(i) **Glutaraldehyde** 2% activated alkaline glutaraldehyde is effective against vegetative bacteria, fungi and most viruses (5-8). A two minute exposure inactivates most infective agents including HIV (9) and enteroviruses (7,10). The hepatitis B virus is destroyed after 2.5 - 5 minutes (11-13). Although possible transmission of HCV has been reported after colonoscopy national guidelines for cleaning were not followed (14). There are no data relating to activity against the hepatitis C virus, but it is likely that this rather fragile agent will be destroyed rapidly. Glutaraldehyde destroys high titres of M. tuberculosis within 20 minutes and lower numbers within 5 - 10 minutes (15,16). M. avium intracellulare is killed after 60 - 75 minutes (17,18) whilst some bacterial spores require three or more hours (19). Although little evidence is available, Helicobacter pylori is likely to be killed rapidly by glutaraldehyde (20), but thorough cleaning is important as this microorganism may be protected by gastric mucus. Prions are mainly present in the brain and nervous tissue of patients with transmissible spongiform encephalopathies e.g. Creutzfeldt-Jakob Disease. Isolation from the blood and other tissues is likely to be rare. There is no current evidence of transmission during gastrointestinal endoscopy. However, prions are resistant to instrument disinfectants, including glutaraldehyde, in the concentrations normally used to disinfect endoscopes (21). They are also resistant to conventional sterilisation processes including autoclaving. Thorough cleaning is essential and should minimise the risk of infection. Endoscopy should preferably be avoided in patients with known or suspected prion disease.

These data suggest that the previous recommendations concerning endoscopy in patients suffering from AIDS or other immunodeficiency states were overcautious. It was stated that endoscopes should be soaked in 2% glutaraldehyde for one hour prior to their use in these immunocompromised patients in order to prevent transmission of infection. The most recent microbicidal data show that a contact period of 20 minutes in 2% glutaraldehyde should be sufficient for disinfection before and after use in patients with symptomatic AIDS or other immunodeficiencies. This contact time is also recommended for clean endoscopes after use in patients with known or suspected mycobacterial infections but an exposure time of 60 - 75 minutes is suggested for M. avium intracellulare (17,18). Furthermore, Hanson et al (7,16) have shown that thorough cleaning of endoscopes removed 3 - 5 log10 of contaminating organisms.

Other aldehydes are available often in combination with other disinfectants. Such combinations are designed to augment antiviral and antibacterial activity and to reduce adverse reactions amongst staff. 'Gigasept' (succine dialdehyde and formaldehyde) is the most widely used. It is, however, inferior in its microbicidal activity to glutaraldehyde at use concentration and longer contact times are
required. In addition, toxic reactions have occurred in exposed individuals. There would seem little advantage for this agent over 2% glutaraldehyde.

The major problem associated with the use of aldehyde disinfectants is that of adverse reactions amongst workers in endoscopy (2). Such reactions present as dermatitis (which may be generalised (22), conjunctivitis (23), nasal irritation (24) and asthma (.25,26). These problems have been long recognised by the Health and Safety Executive.

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 risks to the health of staff by exposure to hazardous chemicals such as glutaraldehyde, 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. Failure to comply with COSHH, in addition to exposing staff to risk, constitutes an offence and renders the employer liable to penalties under the Health and Safety at Work Act 1974. There are specific criteria relating to exposure levels. These are defined in terms of average occupational exposure standard (OES) and maximum exposure level (MEL). 'OES' is the atmospheric level down to which exposure must be reduced. Some leeway is allowed to employers as long as a schedule is put in place until required levels are actually achieved. 'MEL' is the exposure which must not be exceeded and employers must reduce exposure to below this level. Glutaraldehyde currently has an OES of 0.2 ppm (0.7 mg/m3). MELs at 0.02 ppm (8-hour time weighted average TWA)) and 0.05 ppm (15 minute reference period) would lead to an improvement in the overall standards of control if this is reasonably practicable.

The Health and Safety Commission's Advisory Committee on Toxic Substances (ACTS) has recommended that:

1. Maximum exposure limits for glutaraldehyde should be established at:
   i 0.02 ppm as an 8-hour TWA;
   ii 0.05 ppm over a 15 minute reference period;
   and that these limits should attract a 'Sen' (sensitiser) notation.
2. Subject to the Commission's approval, the existing OES for glutaraldehyde will be withdrawn in the 1998 issue of EH40; and
3. HSE will publish guidance on the control of exposure in 1999. The withdrawal of the OES will mean that all exposures to glutaraldehyde will have to be adequately controlled and that exposures meeting the OES will be deemed no longer to be adequate control.
COSHH obliges the employer to make a systematic assessment of risk to staff of exposure to glutaraldehyde and to institute measures to deal effectively with exposure. The action which should be taken is shown in Tables 1 and 2. There are several aspects of COSHH regulations which create problems for endoscopy units and operating theatres.

Table 1
COSHH Regulations for Hazardous Substances

1. Remove the hazardous substance by substituting a safer material or changing the process.
2. When this is impractical exposure should be controlled by enclosing the process, using extraction and ventilation equipment, and adopting safer working and handling procedures. Personal protective equipment may be used to achieve adequate control when other measures are not reasonably practicable, or as an addition to other measures to achieve adequate control.
3. Ensure that control measures are properly used, maintained and tested. Local exhaust ventilation systems installed as a control measure must be examined and tested at least every 14 months.
4. Monitor staff exposure and perform health surveillance.
5. Educate staff on the risks and appropriate precautions to be taken.

Table 2
Personnel Protection in Endoscopy

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

1. Some units still use open baths or semi-automated systems for cleaning and disinfection with no facilities for removal or containment of toxic vapour. This practice must be discontinued.
2. In reality ventilation is often far from ideal and the use of ventilation/extraction systems to protect the cleaning area is not universal. Glutaraldehyde should be activated, used and discharged within the influence of a containment or local exhaust system.

3. Some enclosed automated cleaning/disinfection machines require manual filling and emptying of disinfectant, exposing staff to direct contact or to vapour.

4. Even in the best equipped units with fully automated, enclosed cleaning systems, accidental spillage may occur.

5. Measurement of atmospheric aldehyde levels, particularly at low concentrations, is difficult. The only reliable method involves the use of impregnated filters followed by assay using high performance liquid chromatography (27).

It is possible that within the next few years the use of aldehydes will be reduced because of these difficulties and safe alternatives are being sought. These alternatives must be at least as effective a disinfectant as glutaraldehyde, be non-damaging to endoscopes, accessories and processing equipment, be non-irritant and non-sensitising to users and should not be expensive. As yet no agent completely satisfies these ideals and it is possible that such a disinfectant will not be found. Almost certainly adequate ventilation and other protective measures will continue to be required for most, if not all, instrument disinfectants.

The recent introduction of automated disinfection machines that use glutaraldehyde in very low concentrations has the potential for reducing the exposure risk to staff. The effectiveness of glutaraldehyde in these machines is maintained by heating acid based formulations to 45° - 55°C and the use of fresh materials for each cycle reduces the possibility of contamination and cross infection. Such developments are to be welcomed but their worth needs long term evaluation particularly as raising the temperature of the disinfectant increases the volatility and may damage the instrument.

In response to the recommendations of the disinfectant manufacturers, the Medical Devices Agency and those responsible for policy formation in other countries, the Working Party recommends an increase in the immersion times in 2% glutaraldehyde between patients from 4 to 10 minutes. This change is not based on new microbiological data and does not mean that patients have been exposed to unnecessary risk in the 9 years since the 4 minute immersion was recommended. It is instead a change mainly for political reasons which may increase the margin of safety while not negating the need for effective cleaning of the instruments before disinfection. The increased use of automated cleaning and disinfection machines and the greater number of endoscopes in service since the previous recommendations were published should enable this change to be introduced without too much difficulty in most endoscopy units. The 20 minute immersion at the end of the session should continue but the between-
patient contact time of 10 minutes should be adequate at the start of a session (Table 3)

Table 3
Recommended contact times for Gastrointestinal Endoscopes
Disinfectant contact times (minutes)

<table>
<thead>
<tr>
<th></th>
<th>2% glutaraldehyde</th>
<th>0.35% peracetic acid</th>
<th>chlorine dioxide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before a session</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Between patients</td>
<td>10</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>End of session</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High level disinfection</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>e.g. Before ERCP</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Before use in immunocompromised patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After patients with pulmonary tuberculosis</td>
<td>20</td>
<td>5*</td>
<td>5*</td>
</tr>
<tr>
<td>After a patient with known infection with M. avium intracellulare on other highly resistant mycobacterium</td>
<td>60-120</td>
<td>5*</td>
<td>5*</td>
</tr>
</tbody>
</table>

* Sporicidal activity is achieved in 10 minutes.

(ii) Peracetic acid Peracetic acid was introduced in 1955 as a disinfecting agent or sterilant, and is mainly used in the food and the sewage treatment industry. It has been used for decontamination of plastic isolators and medical equipment, but rarely in the UK. Its constituents are hydrogen peroxide and acetic acid and, as a concentrate, it is corrosive and irritant. It acts by releasing free oxygen and hydroxyl radicals and decomposes to oxygen, water and acetic acid.

Peracetic acid has rapid activity against vegetative bacteria, fungi, bacterial spores and viruses (28–31). Vegetative bacteria, including mycobacteria, are killed in under 5 minutes and Bacillus subtilis spores are destroyed in less than 10 minutes. There are two commercially available preparations: 0.2% peracetic acid (‘Steris’) has been shown to reduce M.tuberculosis and M.avium intracellulare by 5 logio in 15 minutes (17) and 0.35% peracetic acid (Nu Cidex) has shown reductions in M.tuberculosis H37Rv, M.avium intracellulare, M.kansasii, and M.chelonae in 4-5 minutes (32). Peracetic acid has been shown also to be active against a range of viruses, including poliovirus, rotavirus (33),
HBV, and HIV (34). Manufacturer's tests using a 0.35% solution have shown log reductions of over 8 in suspension and surface tests with herpes simplex and poliovirus in less than 5 minutes immersion. Prevention of excystation of cryptosporidium has been reported with 0.2% and 0.35% solutions (35).

Unlike 'Nu Cidex', the 'Steris' peracetic acid can be used only in a dedicated machine (Steris System Processor) (36). This utilises 0.2% peracetic acid at an elevated temperature of 50°C in an enclosed machine. The disinfectant exposure time is 12 minutes with an overall process time of approximately 30 minutes. The machine is not marketed as a washer/dischinfecter but as a steriliser as it uses a sporicidal agent, once only, and rinses processed items in sterile (bacteria free) water. The disinfectant, 35% peracetic acid, is supplied in a twin compartment, single dose, carton. This is punctured automatically when it is placed in the machine. As filtered water enters it dissolves the constituents and produces a working strength of 0.2% peracetic acid. The unit would appear to be user-safe and highly effective in disinfecting/sterilising flexible and heat sensitive rigid endoscopes but it is expensive, takes only one flexible endoscope at a time and the long-term effects on some endoscope components are yet to be established.

'Nu Cidex' is provided in a double compartment container. It is activated when the 5% peracetic acid concentrate in one compartment is released by the user into the buffered stabiliser/corrosion inhibitor in the other compartment. The container is designed so that the user does not come into contact with the solution until the use concentration of 0.35% is achieved. The in-use concentration is said to be non irritant but there is an unpleasant vinegar-like smell.

During the first year or more of its use in the UK and Ireland in more than 180 hospitals there were 12 customer complaints about 'Nu Cidex', 5 concerning adverse health reactions to the product (personal communication Johnson and Johnson Ltd). The symptoms of these reactions have included runny nose, stinging eyes and a 'clawing' sensation in the throat. In all cases it is claimed that the occupational exposure standard (OES) of the ingredients, i.e. hydrogen peroxide and acetic acid were not exceeded and the calculated level of peracetic acid in the atmosphere was almost negligible. It is believed that peracetic acid can exacerbate the symptoms of coryza and influenza. It would seem unwise therefore to recommend that 'Nu Cidex' can be used safely without adequate ventilation and personal protective measures. In a recent survey conducted by the BSG Associates Group (as yet unpublished) 15 of 106 respondents reported they had tried or were using Nu-Cidex as a glutaraldehyde alternative. Six of these reported irritancy problems, eight stated that in their opinion, ventilation was required, six were concerned with processor compatability and five with endoscope compatability. Two of the 15 users reported no problems. There were too few users of other glutaraldehyde alternatives to comment on compatability and irritancy problems. Whether allergic and direct toxicity will prove less with peracetic acid than with glutaraldehyde is as yet uncertain.
'Nu Cidex' is less stable than glutaraldehyde and, once prepared, requires replacement every 24 hours; thus storage of the containers can be a problem when space is limited. It can be used repeatedly over 24 hours providing dilution is not excessive. It is also considerably more expensive than glutaraldehyde but if sensitivity reactions and subsequent compensation claims prove to be significantly less frequent it may prove to be an important advance.

There is concern about the effect of 'Nu Cidex' on some disinfection machines which contain polymer-based seals and brass components within the hydraulic circuit. These are adversely affected after prolonged exposure (personal communication Olympus KeyMed Ltd) to peracetic acid. Information regarding automated machines produced by other companies is unavailable at present. It should be borne in mind that the disinfectant is in contact with processing equipment for much longer periods than the endoscope or accessories. 'Nu Cidex' also causes discoloration and peeling of electro-plated components and of the bending section of endoscopes but these effects appear to be purely cosmetic and have no functional consequences.

Provided this is confirmed by current trials, peracetic acid could be used as an alternative to glutaraldehyde. The manufacturer recommends exposure times for 'Nu Cidex' of 5 minutes for disinfection and 10 minutes for sterilisation. The Working Party recommends a 5 minute immersion time for bactericidal and virucidal activity. However, if sporicidal activity is required, a 10 minute immersion time should be used.

(iii) Peroxygen compounds 'Virkon' is a stable peroxygen disinfectant which is effective against most vegetative bacteria and viruses, but has proved less effective than glutaraldehyde against mycobacteria (18,37) and enteroviruses such as poliovirus (10). Furthermore, some peroxygen compounds affect the components of endoscopes and automated processing equipment. The Working Party does not recommend peroxygen disinfectants for gastrointestinal endoscopy.

(iv) Chlorine dioxide Chlorine dioxide and other chlorine releasing agents have been used for slime control and treatment of drinking and waste water. Instrument disinfectants known as 'Tristel', 'Dexit' and 'Medicide' are commercially available. These products comprise two components, a base and an activator, requiring addition and dilution in accordance with the manufacturers’ instructions, ie 1 part base, 1 part activator and 8 parts water. Errors in the preparation are possible although this criticism does not apply to 'Tristel' and 'Medicide' as these are supplied at their use concentrations.

Freshly prepared chlorine dioxide is highly effective and rapidly destroys bacterial spores, ie B.subtilis and other non-sporing bacteria, including M.tuberculosis, M.avium intracellulare, other atypical mycobacteria and Pseudomonas
aeruginosa. The spores of B. subtilis are very resistant to disinfectants and, as such, provide a very discriminatory and stringent test for new disinfectants (19). Sporicidal activity is maintained for 7 - 14 days provided the disinfectant is stored in sealed containers with minimal head space above the solution (38). This requirement will be difficult to attain in many automated washer/disinfectors and further tests will be necessary to assess stability over a 14 day period. When used according to the manufacturers' prescribed conditions, sporicidal activity is substantiated in 10 minutes and bactericidal and virucidal activity in 5 minutes (the same time as 'Nu Cidex').

Although 'Tristel', 'Dexit' and 'Medicide' are described by the manufacturers as user safe, strong fumes of chlorine dioxide are given off during preparation and use. As with other respiratory irritants these can be substantially reduced if enclosed and/or exhaust ventilated facilities are used. The fumes are unpleasant but tests commissioned on behalf of the manufacturers have shown the level of ClO2 given off to be below the exposure limits set by the HSE in EH40/95. It is strongly recommended by the Working Party, however, that vapour emissions are extracted and/or suitably contained.

Chlorine dioxide is also more damaging to instrument and processor components than glutaraldehyde. As far as is known, none of the leading endoscope manufacturers has completed compatibility tests with instrument components. Experience with chlorine dioxide has demonstrated discoloration of the black plastic casing of flexible endoscopes but this change may be only cosmetic. If chlorine dioxide is used in automated washer disinfectors component contact times are likely to be much longer and, therefore, damage is even more likely. Some material compatibility tests have been carried out by Birmingham University and a summary of this work is available from the disinfectant suppliers.

(v) Quaternary ammonium compounds These are relatively non-toxic and non-damaging but usually have deficiencies in their antimicrobial spectrum. The previous Working Party stated that 'Dettox' (now 'Dettol ED') based upon a combination of quaternary ammonium compounds, EDTA and surfactants, could not be recommended for routine use because of poor virucidal activity. An improved product, 'Sactimed' (‘Sinald’), shows a moderate mycobactericidal effect (18,39), but evidence of effectiveness against enteroviruses is lacking. It cannot be recommended therefore as a disinfectant for gastrointestinal endoscopes.

(vi) Alcohol The previous Working Party recommended 70% alcohol as second choice disinfectant. This is at least as effective as glutaraldehyde in its activity against vegetative bacteria, including mycobacteria, and against viruses, with the exception of rather slower activity against enteroviruses (10). It does not, however, destroy bacterial spores but these are not usually associated with post endoscopic infection.
Unfortunately, prolonged exposure to 70% alcohol disrupts adhesives used in flexible endoscopes damage seal and denature some plastics. Although it can be used for flushing and drying endoscope channels and for wiping the control section and insertion tube of the instrument, the problems with longer exposure and the fact that alcohol is a fire hazard make it an inappropriate choice for use in automated washer/disinfectors. Alcohol may have a role in flushing endoscope channels to dry them prior to storage (40). Seventy percent ethanol, isopropranol and industrial methylated spirits have been used for this purpose.

(vii) Superoxidised water (Sterilox) Sterilox is an ionised salt solution (anolyte) produced by an electrochemical apparatus and contains a mixture of radicals with strong oxidising properties. The solution is generated at or near the point of use, is used once only and should not be stored for more than 24 hours at room temperature. Sterilox is highly microbicidal and similar in efficacy to other glutaraldehyde alternatives such as peracetic acid and chlorine dioxide. To ensure a full microbicidal effect, it is essential that items are cleaned thoroughly and all the manufacturer’s production criteria are met, i.e. generating current, redox potential and pH.

Freshly generated Sterilox has been shown to be more rapidly sporicidal and mycobactericidal than 2% glutaraldehyde under conditions of no or minimal soiling. (Personal communication: JR Babb, CR Bradley and PA Griffiths. Hospital Infection Research Laboratory, Birmingham UK.) A >6 Log10 reduction in Bacillus subtilis spores, and a >5 Log10 reduction in Mycobacterium tuberculosis and Mycobacterium avium intracellulare is achieved in under 5 minutes.

At present experience with Sterilox in the hospital setting is limited and installation requires a radical re-think of current disinfection methods as well as careful costing. If field trials show it can be reliably and economically generated on site and the manufacturer can establish it does not damage endoscopes and processing equipment, it could enhance greatly the automated process of endoscope disinfection and be considered alongside other alternatives to glutaraldehyde.

Use of new disinfectants

The aldehyde disinfectants currently in use are irritant and sensitising but alternatives that are safer to use may be less effective as disinfectants or may damage endoscopes and processing equipment. If an alternative to glutaraldehyde is to be tried, the Working Party endorses the advice given by Babb and Bradley in 1995 (34).:

1. Inform the instrument and processing equipment manufacturers as use of an alternative to glutaraldehyde may invalidate guarantees and/or service
contracts. (Most manufacturers are only too willing to assist and may agree to check instruments and processing equipment periodically for signs of damage.)

2. Carefully cost the change, bearing in mind the use life of the disinfectant.
3. Ensure that processed items are thoroughly cleaned and that the manufacturers' stated contact times are achieved unless advice from professional organisations is available.
4. Establish what is required in terms of COSSH regulations, ie ventilation, personal protective clothing, and ensure that these are properly costed.

Keep the BSG, the Microbiology Advisory Committee to the Department of Health, reference centres and disinfectant and instrument manufacturers informed of your experience, be it favourable or not.

**Sterilisation options**

Unfortunately flexible endoscopes will not tolerate high processing temperatures i.e. in excess of 60°C, and cannot therefore be autoclaved or disinfected using hot water or subatmospheric steam. They may be sterilised, however, by other means provided they are thoroughly clean and the manufacturers' processing criteria are met. Sterilisation options include:

**Ethylene Oxide**

Low pressure or subatmospheric ethylene oxide sterilisers operating at temperatures below 60°C are suitable for sterilising most flexible endoscopes provided an EO venting cap is fitted in accordance with the manufacturers' instructions and the instrument is suitably packaged or contained. However, very few hospitals have an ethylene oxide steriliser. the gas is dangerous and should only be used where suitable equipment, strict environmental controls and specially trained staff are available. Biological indicators are required for routine monitoring.

This process is unlikely to be suitable, if a quick turn around of instruments is required, due to the lengthy periods (1-7 days) required for processing, the incubation period for indicators and aeration to remove gaseous residuals. Further advice on this method of sterilisation is contained within the Medical Devices Agency Guidance on Decontamination of Endoscopes from the Microbiology Advisory Committee (4).

**Gas Plasma**

This is a highly excited body of gas produced by the application of energy to a gas under vacuum, making ions and molecules within the plasma collide to produce free radicles. These interact with microorganisms to disrupt their function. The most well-known system is Sterrad TM which utilises a low temperature (<50°C) hydrogen peroxide gas plasma. The manufacturers (Advanced Sterilisation Products) claim that flexible endoscopes may be
processed using this particular system but special adapters (H2O2 boosters) are required for use with lumened devices to ensure the disinfectant or sterilant gains access to these areas. Very long narrow lumens, and those closed at one end, are unsuitable for sterilisation using gas plasma. The endoscope must be thoroughly clean and dry before sterilisation and process-compatible packaging materials must be used. The entire cycle takes only 75 minutes but, as with ethylene oxide, biological indicators are required for routine monitoring and these require lengthy incubation periods. Although no toxic emissions result from the process, these technical problems, especially the long cycle time, make gas plasma impractical for routine processing of most gastrointestinal instruments.

**Automated endoscope washer/disinfectors**

These have become an essential part of most endoscopy units as they increase instrument throughput and reduce staff contact with disinfectant (41). The machine must be effective, safe, reliable and able to cope with endoscope design and throughput. Several endoscope washer/disinfectors of different design are available. They do not negate the need for manual cleaning of the insertion tube, suction/biopsy channel, instrument tip and valve recesses, but do offer several advantages:

a. They ensure complete irrigation of all channels i.e. biopsy, suction, air, water, auxiliary water, CO2, although the bridge raiser channel on duodenoscopes cannot be irrigated by most currently marketed machines.

b. They offer a more reliable and reproducible decontamination procedure than manual processing and are more convenient for endoscopy staff.

c. They reduce the likelihood of eye, skin and often respiratory exposure to the disinfectant.

Endoscope washer/disinfectors also have some disadvantages:

a. Regular maintenance is required to ensure tanks, pipework, strainers, filters and other machine components are free from deposits, biofilm and limescale.

b. Processed endoscopes may become recontaminated during the rinsing stage of the cycle either from the machine or the water supply. The Department of Health recommends pre-pre-sessional disinfection of the machine which should include all fluid pathways (4,42). Pseudomonas aeruginosa, other Gram-negative bacteria and atypical mycobacteria have been isolated from machines and rinse water. These have led, on occasions, to machine infection and 'pseudoinfection'. Some machine isolates of Mycobacterium chelonae are extremely resistant to glutaraldehyde, and an alternative disinfectant, i.e. a chlorine releasing agent or peracetic acid, should be used for machine disinfection (42,43). The water used for the final rinse should be of a suitable quality for the endoscopes being processed and therefore a water treatment system may
be required. Water softeners, membrane cartridge filtration down to 0.2u, ultraviolet light and heat treatment have all been used to prevent contamination with limescale biofilm and microorganisms.

c. Manual cleaning of the endoscope remains an essential pre requisite to automated cleaning and disinfection.

d. If no provision is made to contain or extract irritant vapour, atmospheric levels may be increased due to displacement of disinfectant laden air when fluids are pumped or drained from compartments of the machine.

e. The machines, exhaust ventilation and water treatment systems are expensive to purchase, install and maintain.

f. Excessive dilution of the disinfectant with a subsequent reduction in potency, may occur due to the carry over of cleansing solution or rinse water (44,45).

g. A build-up of disinfectant will occur if the rinse water is reused. This may transfer toxic residues to the endoscope and cause irritation of the patient's mucosa or endoscopist's eyes. It is preferable that the rinse water is not reused.

Some special features or performance characteristics are optional but all machines should clean, disinfect and rinse all internal channels and external surfaces of the range of endoscopes used in accordance with local Hospital Infection Control Committee protocols and/or national guidelines. Instructions and training should be given by the machine manufacturers on how to connect the instrument to the washer/disinfector to ensure all channel irrigation. The machine should be programmable to accommodate the disinfectant contact times 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. Other features to consider when purchasing a machine are:

a. the number of endoscopes which can be processed simultaneously.

b. a cycle counter and fault indicator.

c. a control system for use when the disinfectant produces an irritating or sensitising vapour. Machines are available which are able to contain and/or condense irritant vapours or will exhaust them either directly to the outside or adsorb them onto a carbon filter.

d. a water treatment system which prevents recontamination of processed instruments during rinsing. Filtration using bacteria retaining filters with a pore size of 0.2 to 0.45u is satisfactory. The use of filters can create additional problems and users should be aware of the need for decontamination of the filtration and water delivery system. Bacteria free water is preferable but not essential for rinsing of gastrointestinal endoscopes except when the endoscope is to be used for ERCP. Bronchoscopes and invasive surgical endoscopes also require bacteria free water. To prevent the build up of disinfectant residues it is preferable that the rinse water is dumped at the end of each cycle.
e. a reliable, effective and simple machine disinfection cycle.
f. an air drying facility to expel fluids and dry the channels of the endoscope at the end of a cycle.
g. a facility to irrigate the channels of the endoscope with alcohol before storage.
h. a leak test facility.
i. a printout of cycle parameters which can be retained for quality assurance records.

It is essential to confirm that a machine is compatible with the disinfectant to be used. The disinfectant will remain in contact with the machine for much longer periods than with the endoscope. Advice on compatibility should be sought from the disinfectant and machine manufacturers. Users are advised to review independent test reports before purchasing automated processing equipment.

**Cleaning and disinfection - practical recommendations**

The cleaning and disinfection 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. If an emergency endoscopic procedure is done out of hours, someone with this knowledge should be available and be responsible for the cleaning and disinfection of the equipment.

The most important aspect of the process is the manual cleaning of instruments with detergent. The aim is to remove all blood, secretions and other organic material prior to the surfaces coming into contact with the disinfectant. If this process is not performed thoroughly, organic material may become fixed and organisms not accessed by the disinfectant. The utmost care must be taken at this stage of the cleaning process. All modern endoscopes are fully immersible but caps must be fitted when required (e.g., with video endoscopes). Manufacturers' instructions must be assiduously followed.

The following recommendations are made for cleaning and disinfection of endoscopes for which an automated system is preferred: at the start of the day.

1. Instruments to be used during the list should be checked for faults.
2. If instruments have been thoroughly cleaned and disinfected at the end of the previous day, they should be put through an automated cleaning and disinfection process (or subjected to a manual disinfection procedure) with, in the case of glutaraldehyde, a 10 minute exposure at the start of the next day. There is no necessity to clean the endoscope channels providing this was done at the end of the previous day.
3. All channels should be flushed with the disinfectant either independently or by using an all-channel irrigator. Care should be taken to ensure disinfectant emerges from all ports on the light guide connector and distal
end of the instrument. Appropriate personal protection must be worn by staff before immersing equipment in disinfectants.

4. The instrument should be fully immersed in disinfectant for the correct contact time; a timer should be used to indicate when the correct time is attained. A variant of this might be to include the endoscope in the self-disinfection cycle of the automated washer/disinfector machine at the start of a day or session, provided an endoscope-compatible disinfectant is used.

5. The raiser bridge or auxiliary channel in some endoscopes requires flushing manually using a 2 ml syringe and a channel adapter. A new syringe should be used for each endoscope.

6. The valves that will be used during the list, ideally one set per case, should be disinfected in the same way.

7. After disinfection, endoscopes and valves should be rinsed in bacteria-free water ensuring that all traces of disinfectant are removed from the channels, control body and eyepiece. Rinse water should be changed frequently to avoid the build-up of toxic disinfectant residues. The endoscopes should be dried carefully and valves inserted.

8. The instrument should then be plugged into the light source and connected to the suction pump. Air should be blown through all the channels to expel excess fluid.

9. The instrument should then be ready for use.

When an automated washer/disinfector is used, steps 3 to 7 will be performed by the machine.

**Cleaning and Disinfection of endoscopes: between cases**

1. Before the instrument is detached from the light source or video processor the air/water channel should be flushed with water for at least 15 seconds to ensure that blood, mucus and other debris are expelled. Some manufacturers provide a special valve for this. The auxiliary washing pipe should be connected to the biopsy port and the suction button depressed for 15 seconds with the distal tip of the endoscope and the washing pipe in clean water to remove gross debris from the suction and biopsy channels. The outer surface of the insertion tube should be wiped to remove organic material. The endoscope may then be disconnected.

2. The instrument should be leak-tested and checked for obvious faults or damage before being immersed in a suitable neutral or enzymatic detergent.

3. The outer surface of the endoscope should be carefully cleaned, particularly around the control section, the angulation controls, the distal end (especially the air/water nozzle) and the bridge mechanism of duodenoscopes, using a soft toothbrush.

4. All valves should be removed and cleaned individually with a cotton wool bud or small brush.
5. The suction/biopsy channel must be cleaned with a flexible brush of the correct size. This is repeated until the cleaning brush appears visually clean at the distal end and light guide connector. The brush is passed through the suction port in two directions, i.e. insertion tube and umbilicus. When it appears at the distal end the brush is cleaned using a soft toothbrush before it is withdrawn. This should be carried out preferably under water to prevent the risk of splashing or aerosol production. Prior to reinsertion the brush is again cleaned using the toothbrush.

6. When the channels have been cleaned the suction and air/water ports must be cleaned with a cotton wool bud or small toothbrush.

7. All channels of the endoscope should be irrigated now with a neutral or enzymatic detergent using an all channel irrigation device. Suction and air insufflation should be used to remove fluid residues.

8. After manually filling any auxiliary or raiser channel with disinfectant, the endoscope can be disinfected in an automated washer/disinfector. If this process is done manually, steps 3 and 4, described previously under 'At the start of the day', should be followed. Once completed all channels must be rinsed with bacteria-free water in the same manner. Air may be blown through the channels at this stage to expel excess fluids which might otherwise dilute the disinfectant (44,45).

9. The endoscope is now ready for disinfection. The instrument must be fully immersed in disinfectant for the correct contact time, ensuring that all channels are filled with disinfectant. A timer will ensure immersion times are correct.

10. The instrument is rinsed as in steps 7 and 8 'At the start of the day'.

11. The relevant work surfaces, such as the top of the endoscopy trolley, should be wiped clean between patients, usually with an alcohol wipe, in accordance with local hospital policy. Once the endoscope has been disinfected, rinsed and dried, fresh valves should be inserted and the instrument placed on the clean surface ready for use.

Cleaning and Disinfection of endoscopes: after the last case

1. Endoscopes used during the list should be leak-tested, cleaned and disinfected. When 2% glutaraldehyde is used the contact time should be 20 minutes, while for peracetic acid and chlorine dioxide this should be for 5 minutes.

2. Endoscopes should be dried before storage. Seventy per cent alcohol may be aspirated through the channels to assist drying. Thorough drying reduces the risk of subsequent microbial proliferation.

3. Endoscopes should then be stored hanging vertically in a designated ventilated cupboard, not in their transit cases.

4. All valves used during the list should, after disinfection and rinsing, be dried with a cotton wool bud and lubricated with silicone oil as instructed by the manufacturer. They should not be replaced in the endoscope case for storage.
Cleaning and Disinfection of Accessories

Accessories require the same attention to detail. Some accessories are single use and, where access for cleaning is difficult or the item is heat sensitive, their use should be encouraged. Cytology brushes, polypectomy snares, injection needles and some ERCP accessories may be purchased as single use. The risk of transfer of infection by re-using possibly contaminated items must be weighed against the cost of single-use accessories. Many accessories are autoclavable and their use should be encouraged; these include water bottles, biopsy forceps, dilators and guidewires. During ERCP, disposable accessories should be used whenever possible or if reusable there should be sufficient autoclavable accessories to allow one per case with no requirement to disinfect during a list.

The Medical Devices Agency Bulletin DB 9501 advises on potential hazards, both clinical and legal, associated with reprocessing and reusing medical devices intended for single use (46). Users who disregard this information, and prepare single use items for re-use without due precautions, may be transferring legal liability for the safe performance of the product from the manufacturer to themselves or their employers.

Biopsy forceps which have a spiral construction and other accessories which are difficult to clean by hand should be ultrasonically cleaned and rinsed prior to autoclaving or disinfection. Other accessories requiring disinfection, including the cleaning brushes themselves, should be cleaned in detergent using a soft brush before disinfection.

Protection of Personnel

It is essential that endoscopy staff have the correct personal protective equipment available at all times and are trained in its use (Table II). Each endoscopy unit must have a policy for dealing with disinfectant spillage and all staff must be trained in its implementation. 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. Training of staff in these aspects of their work is vital.

Table 2
Personnel Protection in Endoscopy

1. Wear disposable waterproof aprons. These should be discarded if soiled with disinfectant.
2. Use nitrile gloves which are long enough to protect the forearms from splashes. These should be changed regularly because they absorb glutaraldehyde.
3. Goggles prevent conjunctival irritation and protect the wearer from splashes.

4. Disposable charcoal-impregnated face masks may reduce inhalation of vapour from disinfectants, but experience with them is not yet widespread.

5. An HSE-approved vapour respirator should be available in case of spillage or other emergencies. It should be stored away from disinfectants as the charcoal adsorbs fumes and respirators should be regularly replaced.

Staff Health

All staff using or coming into contact with glutaraldehyde should be included in a health screening programme which comprises:
- Pre-employment enquiry regarding asthma, skin and mucosal symptoms, such as rhinitis and conjunctivitis, and lung function testing by spirometry.
- Annual lung function tests by spirometry.
- Annual completion of a health questionnaire.
- Immediate notification of skin rashes, chest and sinus problems.
- Records must be kept for 30 years.

It is recommended that this policy is extended to include other disinfectants used in endoscopy because hazards associated with the alternatives are largely unknown. In addition, although endoscopy is not a designated 'exposure prone procedure' (personal communication, Chief Medical Officer) it is strongly advised that all staff involved in endoscopic practice should be vaccinated against hepatitis B. Other recommendations relating to risk of needle stick injury and hazards relating to open cuts, abrasions and other skin lesions, reported by the previous Working Party, remain unchanged.

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