Cleaning and disinfection of equipment for gastrointestinal flexible endoscopy: interim recommendations of a Working Party* of the British Society of Gastroenterology

Introduction and background

At a symposium on safety in endoscopy held at the 1986 autumn meeting of the British Society of Gastroenterology in Cardiff, concern was expressed regarding the risk of patient to patient transfer of human immune deficiency virus (HIV) infection during routine gastrointestinal (GI) flexible endoscopy lists, particularly from the unidentified carrier. As a result a Working Party was set up to examine ways in which the recommendations of the Endoscopy Committee of the British Society of Gastroenterology (BSG) published in *Gut* 1983† should be amended to prevent patient to patient, and patient to staff transmission of HIV, hepatitis B virus (HBV) and other pathogens. The 1983 report was published before immersible flexible endoscopic equipment was available and at a time when risks of HIV infection were not appreciated.

The following Working Party report was accepted by the Endoscopy Committee and Council of the BSG in 1987. Because rigid endoscopic equipment (procto-sigmoidoscopy, laparoscopy) is routinely sterilised this report is limited to the use of flexible GI endoscopes.

Five main areas require attention:

1. Is a two tier system of disinfection, as outlined in the 1983 document, still appropriate? This document suggested a short between case disinfection for all cases, and an upgrading of those procedures in the case of ‘identified’ individuals infected with HIV, HBV or other communicable pathogens.

2. A recommended minimum disinfection time is required, based on current *in vivo* and *in vitro* data and avoiding excessive margins ‘for safety’, which would make routine implementation impractical for gastrointestinal endoscopy.

3. Recommendations on cleaning and disinfection of ancillary equipment and the precautions to be taken by endoscopic staff need to be re-examined.

4. Clear guidelines are required concerning the nature and use of disin-

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fectants. The problem of glutaraldehyde sensitivity was understated in the 1983 document. Recommendations are needed to prevent sensitisation of new staff and an effective second line disinfection procedure is required to protect staff already sensitised to glutaraldehyde.

5 Precautions have to be taken to prevent the transmission of HIV, HBV, and other organisms to staff.

6 Gastrointestinal endoscopy staff require education and training in the cleaning and disinfection of instruments and safety within the endoscopy unit, so that recommendations can be generally implemented.

**Two tier system of cleaning and disinfection v an upgrading of routine procedures**

Human immune deficiency virus infection is well established in the UK, with a seropositivity rate of 25–30% in homosexual men attending London sexually transmitted diseases (STD) clinics, 4–11% in those in the provinces, 4–50% of intravenous drug users in different cities and an increasing number of heterosexual cases being identified. It has been estimated that up to 34% of those infected may progress to full AIDS in three years. At a given time most chronically infected individuals will be asymptomatic. Only anti-HIV testing in the form of routine screening would detect the majority of infected persons. Even then, a small percentage of individuals would be infected and have no detectable antibody (being in the short serological window of acute infection or having a more delayed antibody response). Moreover, new but related viruses have been identified in Africa and Europe, antibodies to which may not be detected in assays at present available for anti-HIV.

The 1983 BSG recommendations and those of the DHSS assumed that high risk individuals – for example, those infected with HIV or HBV – could be easily identified. Under those circumstances an upgrading of routine practices was advised to prevent patient to patient, and patient to staff transmission. The advice included thorough cleaning followed by exposure for at least two hours to disinfectant, or sterilisation using ethylene oxide. The current DHSS guidelines recommend a presoak for one hour in glutaraldehyde, thorough cleaning, and a further three hours’ exposure to glutaraldehyde.

This Working Party believes that the identification of all at risk individuals by history and examination is not possible. Moreover, universal screening, with its potential legal and social consequences, is not recommended. Even if implemented, screening would not identify all infected patients and would not necessarily diminish the risk of transmission. Similar conclusions have been reached by bronchoscopists in the UK. The Working Party therefore recommends that all patients are considered at risk and adequate antibacterial and antiviral disinfection is needed before and after each GI endoscopy.

The cleaning and disinfection times at present recommended for patients infected with HIV could not be incorporated into routine practice without either a marked reduction of patients on endoscopic lists, or unrealistic expenditure on equipment. The Working Party have therefore reviewed the available evidence for the effectiveness of commonly used disinfectants and cleaning and disinfection techniques.
Disinfectants

Thorough manual physical cleaning of the instruments, internally and externally with detergent before disinfection, is the most important part of the cleaning and disinfection procedure. Mechanical cleaning and washing with detergent removes adherent debris, and large numbers of microorganisms. Cleaning alone with neutral detergent has resulted in a 2.5 mean reduction in log bacterial counts from brush samples in an automated system. A disinfectant will be ineffective if microorganisms are shielded from contact by organic material. For example, cross infection has been documented when inadequate physical cleaning was followed by ethylene oxide sterilisation.

Activity against viruses

There are problems in interpreting the limited disinfection data on the two viruses most pertinent to this document – namely, HBV and HIV. There are little in vitro or in vivo available data on either, and as HBV cannot be propagated in tissue culture, virucidal testing cannot be carried out as it can be for other viruses.

Although evidence of effectiveness of routinely used concentrations of disinfectant is required, some extrapolation is possible from tests with other viruses. Human immune deficiency virus appears to be similar to other enveloped viruses, and it has been suggested that polio virus may be similar in its response to disinfectants as HBV. Dried suspensions of herpes and polio virus in 10% serum are readily inactivated by 2% glutaraldehyde in one minute (Ayliffe personal communication).

Although in vitro experiments examining the action of common disinfectants on the titre of viral proteins and HBV-DNA polymerase enzyme activity have been described, their relevance to the clinical situation is uncertain. For example, the HBV-DNA polymerase assay requires pre-treatment of virus particles with a non-ionic detergent to disrupt the viral coat and expose the enzyme. This step alone may decrease (if not abolish) infectivity, yet data obtained by this method have been used to indicate the effectiveness of disinfectants such as ethanol in the clinical situation. The virucidal activity of common disinfectants in vitro is largely mediated by their action on the envelope or coat of the virus rather than inactivation of an enzyme in the core of the virus particle.

The lack of data in the case of HBV has led experts to over compensate by recommending high level disinfection and even sterilisation, fostering the concept of a 'super virus' in terms of its resistance to disinfectants. The available in vivo data do not support this concept (Table 1). Hepatitis B virus in dried human plasma (10⁹ chimpanzee infectious doses/ml) has been exposed for 10 minutes at 20°C to isopropyl alcohol (70%), alkaline glutaraldehyde (Cidex) 2%, and a 1:16 dilution of Sporicidin. With alcohol and Cidex, no HBsAg was detected in the plasma pool after treatment, but with Sporicidin there was some remaining HBsAg reactivity by RIA (but only four sample ratio units). None of the treated plasma pools, however, infected chimpanzees (one per disinfectant). The same inoculum treated with saline infected both the control animals inoculated.

In similar experiments, using a highly infective pooled human plasma containing 10⁹ chimpanzee infectious doses/ml, 1% and 0.1% aqueous
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Table 1  Activity of disinfectants against HBV and HIV

<table>
<thead>
<tr>
<th>Virus</th>
<th>Method</th>
<th>Disinfectant</th>
<th>Exposure time (mins)</th>
<th>Outcome</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBV</td>
<td>Highly concentrated virus preparation</td>
<td>70% isopropyl alcohol</td>
<td>10</td>
<td>No infection*</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>80% ethyl alcohol</td>
<td>2</td>
<td>No infection†</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2% alk. glutaraldehyde</td>
<td>10</td>
<td>No infection*</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1% alk. glutaraldehyde</td>
<td>5</td>
<td>No infection†</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0-1% alk. glutaraldehyde</td>
<td>5</td>
<td>No infection†</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1-16 Sporicidin</td>
<td>10</td>
<td>No infection*</td>
<td>17</td>
</tr>
<tr>
<td>HIV</td>
<td>Reverse transcriptase activity in viral culture</td>
<td>19% ethyl alcohol</td>
<td>5</td>
<td>99% inactivation</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25% ethyl alcohol</td>
<td>5</td>
<td>inactivation</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0-0125% alk. glutaraldehyde</td>
<td>60</td>
<td>95% inactivation†</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Highly concentrated virus preparation in vitro infectivity assays</td>
<td>70% alcohol</td>
<td>1</td>
<td>No infection</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50% ethyl alcohol</td>
<td>2-10</td>
<td>No infection</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0-08% QAC</td>
<td>10</td>
<td>No infection</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>*One animal challenged</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>†Two animals challenged</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>‡Much of enzyme activity lost in first five minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| QAC=quaternary ammonium chlorides

glutaraldehyde at 24°C for five minutes and ethyl alcohol (80%) at 11°C for two minutes inactivated HBV. Two animals were challenged with each disinfectant treated inoculum without infection.18

Human immunodeficiency virus is inactivated by commonly used disinfectants (Table 1). Using a highly concentrated viral preparation, many orders of magnitude above those commonly found in patient derived specimens, viral infectivity was undetectable and reduced by more than 7 log10 TCID 50 (TCID 50=tissue culture infectious dose, the reciprocal of the dilution at which 50% of cultures are positive) within one minute with ethyl alcohol (70%) or a non-ionic detergent (Nonidet-P40) and within 10 minutes with a 0-08% combination of quaternary ammonium chlorides.19 In similar experiments ethanol (50%) completely inactivated HIV in two to 10 minutes.20 In a different approach using the reverse transcriptase (RT) assay, which is less sensitive than those quoted above, a high sensitivity to very low concentrations of glutaraldehyde (0-0125%) was shown, with much of the enzyme activity lost in the first five minutes. After five minutes’ treatment with ethanol (19%), RT activity was 1%. These authors suggested that ethanol (25%) or 1% fresh activated glutaraldehyde should be effective for disinfecting medical instruments.21

ALDEHYDE PREPARATIONS

Two per cent activated alkaline glutaraldehyde (Cidex, Totacide and Asep) is widely used for disinfection of fibreoptic endoscopes.22 It provides a wide spectrum of activity against bacteria and their spores, against viruses and fungi, and is non-corrosive. Its irritant and allergenic properties have precluded its use in many departments, however, and second line disinfection procedures are in use, not all of them adequate.

Other aldehyde preparations such as Gigasept, containing Butan 1–4 Dial/2,5 dimethoxy tetra-hydrofuran and formaldehyde and Sporicidin (0-125% glutaraldehyde and 0-44% phenol when diluted for use) are available. They are promoted as being less toxic (both are diluted for
disinfection), but more information is required to confirm this. Gigasept is highly effective in destroying vegetative bacteria and viruses and a 10% concentration is recommended. Gigasept 5% has been shown to inactivate hepatitis B virus in a transmission experiment. Only one chimpanzee was used and the exposure time was one hour.\textsuperscript{21} Shorter exposure times have not been evaluated. Recently, however, Gigasept (5%) has been shown to inactivate HIV within five minutes using both reverse transcriptase and \textit{in vitro} infectivity assays (Kurth R, report in the files of Sterling-Winthrop). Again shorter exposure times have not been evaluated. Experiments with Sporicidin diluted to 1:16 have shown that it is less effective than ethyl alcohol (70%), glutaraldehyde (2%) and Gigasept in reducing bacterial counts (largely gram negative bacilli such as pseudomonas) from brush samples of the suction/biopsy channel in an automated system\textsuperscript{15} and cannot be recommended. It might be assumed that the same inadequacy would apply to its antiviral activity. Exposure of highly infectious human plasma containing HBV to Sporicidin 1:16 for 10 minutes and glutaraldehyde (0.1%) for five minutes, however, prevented HBV transmission to chimpanzees\textsuperscript{17} and HIV has been shown to be sensitive to low concentrations of glutaraldehyde (0.0125%) using a reverse transcriptase assay, although this is less sensitive than infectivity assays.\textsuperscript{21}

\textbf{The Working Party recommends \textit{alkaline} glutaraldehyde (2\%) and Gigasept (10\%) as effective antibacterial and antiviral disinfection agents.}

\textbf{Staff sensitivity to aldehydes}

There is a high incidence of sensitivity in British endoscopy units to aldehyde disinfectants. A questionnaire survey in 1981 suggested that 16 of 43 (37\%) of units had experienced problems with staff becoming sensitive.\textsuperscript{24} As a result alternative disinfection procedures are in use which (in the light of our report below), cannot be regarded as adequate. It is pertinent, therefore, to consider the special precautions which are needed to protect staff. The problems highlighted by the 1981 survey may reflect inadequate precautions and sensitivity in some cases may really be toxicity. Sensitivity arises from splashing, which can affect the eyes, from hand immersion and from inhalation of vapour. Sensitivity reactions include dermatitis, which can occur in skin remote from contact with the disinfectant, conjunctivitis, nasal irritation, sinusitis, and asthma.\textsuperscript{25,26}

A Health and Safety adviser has recently conducted experiments in a large (60 m\textsuperscript{2}) endoscopy suite in which staff had complained of symptoms compatible with excessive aldehyde exposure (R Leicester, personal communication). The disinfectant in use was a 10\% solution of Gigasept. Two direct reading instruments were used to measure formaldehyde concentrations and the source of contamination was found to be a manual cleaning endoscope bath. The short and longterm exposure limits set by the Health and Safety Executive (HSE) (short term 2 ppm averaged over 10 minutes and long term 2 ppm averaged over eight hours\textsuperscript{7}) were considerably exceeded. (The United States equivalent of HSE, the National Institute for Occupational Safety and Health (NIOSH), has control limits of 1 ppm for long and short term exposure.) After the use of an automatic washing machine and an autodisinfector where solutions were pumped in and drained into enclosed containers, concentrations were well below the HSE and NIOSH limits.
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Unfortunately there is at present no easy routine method for measuring glutaraldehyde concentrations (K Allner, Safety Officer, Centre for Applied Microbiological Research, Porton Down, personal communication). The method recommended by the Health and Safety Executive for measurement of formaldehyde is not suitable for glutaraldehyde. Aldehyde disinfectants should preferably be used in a closed system.

**Suitable exhaust extraction facilities such as hoods or cabinets or closed circuit washing machines should be provided in work areas. Ordinary rubber gloves are not sufficient protection.** Viton and nitrile rubber show the best resistance to organic chemicals. In addition, suitable eye protection should be provided where splashing might occur.

**Alcohol.** Various alcohols (ethyl, isopropyl) have been used for disinfection. Isopropyl alcohol (70%) and ethanol (80%) inactivated HBV within 10 and two minutes respectively in chimpanzee transmission experiments. Ethanol (70%) and (50%) inactivated HIV in *in vitro* infectivity studies within one and two to 10 minutes respectively and 25% ethanol has been recommended by other investigators on the basis of a less sensitive *in vitro* assay. Seventy per cent alcohol can therefore be recommended as an antiviral disinfectant.

Experiments with ethyl alcohol (70%) have shown that it is as effective as glutaraldehyde (2%), Gigasept (10%) and quaternary ammonium compounds (Dettox) in reducing bacterial counts (largely gram negative bacilli such as pseudomonas) from brush samples of the suction/biopsy channel in an automated system. A number of earlier studies suggested that 70% alcohol alone was not a suitable general disinfectant for endoscopy, however, as vegetative organisms – for example, pseudomonas, may not be satisfactorily eliminated and sepsis and death have occurred in patients undergoing ERCP.

Major instrument makers have previously recommended against soaking fibreoptic instruments in 70% alcohol because of possible deterioration of the adhesives used in endoscopes and also in some of the flexible plastics and rubber seals. Manufacturer’s tests have mainly used isopropyl alcohol, but ethyl alcohol has similar effects. Seventy per cent ethyl alcohol has been recommended for use only in perfusing and soaking the Teflon instrument channels, providing these were thoroughly rinsed and dried afterwards, and also for wiping the control section of the instrument because alcohol does not damage rigid plastics or metal parts. This limited procedure, in conjunction with quaternary ammonium compounds (see below) has been used in a number of units for disinfection without problems, although it should be remembered that concentrated alcohol carries a fire hazard and has to be used and stored with suitable care.

Previously the major problem with recommending 70% ethanol as a second line antiviral disinfectant for endoscopy has been the contravention of manufacturers’ recommendations. Three major instrument manufacturers (Olympus, Fujinon and Pentax) have recently approved the use of 70% ethyl alcohol for repeated soaks, up to four to five minutes each, of the endoscope shaft and tip, if followed by thorough rinsing and drying; the control body of these instruments must still be wiped and not immersed in
70% alcohol to avoid damage to water proofing seals. Another instrument manufacturer (Machida) does not approve.

For appropriate instruments, and with the reservation that total immersion is impossible, 70% ethanol can be recommended as a second line antiviral disinfectant.

QUATERNARY AMMONIUM COMPOUNDS
An alternative antibacterial disinfectant used in the United Kingdom is Dettox (based on the combination of quaternary ammonium compounds EDTA and surfactants, which considerably improves its activity against vegetative bacteria, especially gram negative bacilli). It is already widely used in endoscopy units as a detergent (0.5%) and a disinfectant (8%). Dettox (8%) disinfects fibrescopes in two minutes as far as bacteria other than mycobacteria are concerned. A 0.08% concentration of quaternary ammonium chlorides has been shown in one report to inactivate HIV in infectivity assays in 10 minutes. Preliminary experiments suggest that HIV may be relatively resistant to Dettox, however (D J Jeffries, personal communication). In the light of this information and the poor activity of quaternary ammonium compounds against other viruses—"the Working Party cannot recommend the use of Dettox alone for viral disinfection, although it is an effective second line antibacterial agent.

CHOICE OF DISINFECTANT
A simple guide to the range of disinfectants in use and their properties, advantages, and disadvantages, is shown in Table 2, together with the four minute immersion time the Working Party recommends. This four minute soak period assumes that the endoscope has been thoroughly mechanically cleaned and treated with detergent before disinfection (see cleaning and disinfection procedures). It also takes into account the available in vitro and in vivo evidence summarised in Table 1 with HBV and HIV preparations treated only with disinfectants (without prior detergent treatment) and incorporates what the Working Party feels is an adequate and practical Table 2  Instrument disinfectants

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>Immersion time (mins)</th>
<th>Activity against:</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aldehydes (2% glutaraldehyde, 10% Gigasept)</td>
<td>4</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>70% ethyl alcohol</td>
<td>4</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>QAC+EDTA (Dettox 8%)</td>
<td>2</td>
<td>+</td>
<td>?</td>
</tr>
</tbody>
</table>

QAC = Quaternary ammonium compounds; ? = requires further investigation
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safety margin. None of the disinfectants shown with a four minute immersion time will be active against spores (several hours of exposure to glutaraldehyde (2%) is required for this).13 In addition, 30–60 minutes is needed to kill mycobacteria13 (see management of HIV infected patient). Further work on the antiviral activity of disinfectants is in progress and future recommendations will change accordingly. Iodine compounds have not been considered by the Working Party because they stain endoscopic components and are not advised by endoscope manufacturers. Use of ethylene oxide sterilisation is not considered in this report, being unnecessary and unrealistically time consuming for routine use.

At present the Working Party considers the only generally acceptable disinfectants for GI endoscopy are 2% glutaraldehyde and 10% Gigasept (four minute soak) because no other single disinfectant is effective against vegetative organisms and viruses and also acceptable to the instrument manufacturers. If, as a result of staff sensitivity, aldehyde disinfectants cannot be used total immersion in 8% Dettox for two minutes followed by 70% ethyl alcohol (usually supplied as 70% methylated industrial spirits BP) for four minutes as detailed above, is an effective second line substitute.

Cleaning and disinfection of endoscopes and ancillary equipment

The risk of cross infection during endoscopy was considered previously when attention was drawn to the numerous reports of patient to patient transfer of salmonella.35 There is one documented case of transmission of hepatitis B at endoscopy.36 A survey carried out in 198124 showed that many endoscopy units in the United Kingdom were using what were considered to be unsatisfactory cleaning and disinfection techniques between cases. As a result the dangers of endoscopic cross infection with HBV and HIV are perceived on theoretical grounds to be very small. The increasing prevalence and serious consequences of HIV infection, however, make considerable improvement in cleaning and disinfection techniques mandatory.

Cleaning and disinfection procedures – general principles

HIV has been isolated from a variety of body fluids and secretions but epidemiological evidence supports the concept that blood and genital secretions are the most important vehicles of transmission. The following general principles apply to endoscopic procedures on all patients.

At endoscopy the risk of HIV infection is likely to be greatest if contaminated equipment is brought into contact with breaks in the epithelial lining of the gastrointestinal tract. The pharynx may be damaged by the tip of the endoscope on insertion; bleeding may occur at the gastrooesophageal junction from retching, and the anus or colorectum may be traumatised by enema preparation, or the insertion of endoscopic equipment. Particular risks may occur if biopsies are taken with forceps either inadequately disinfected, or passed through contaminated biopsy channels. For similar reasons there may be risks with therapeutic procedures such as polypectomy, sphincterotomy, stricture dilatation, and especially injection of oesophageal varices and vascular anomalies. Bearing these particular problems in mind, special attention should be paid to thorough cleaning and disinfection of the instrument tip, the shaft, the suction/biopsy channel and biopsy valve.
mechanism, as well as of the ancillary equipment which is passed through the biopsy channel. As indicated above, the Working Party believes that the risk of transmission of HIV virus is small, provided that appropriate care is taken with cleaning and disinfection. It is difficult to make specific recommendations which are applicable in all circumstances. This report offers general advice and important principles in connection with cleaning and disinfection, together with some explanation of the principles on which it is based.

Cleaning and disinfection of GI endoscopic equipment is a specialised procedure and should be carried out only by staff who have been properly trained. Where emergency GI endoscopy services are provided fully trained assistants should be available on call to assist with the endoscopic examination and the cleaning and disinfection of the equipment used.

The Working Party reaffirms that all endoscopic equipment should be thoroughly mechanically cleaned with detergent and be disinfected before the endoscopy list begins, between each patient examined, and at the end of the list. The most important procedure is the mechanical cleaning of the endoscope to remove all blood, secretions and organic material, as the presence of these will prevent adequate penetration of the disinfectant, and the exposure time required may be many times that recommended for bacterial or viral inactivation. Enzyme cleaning preparations may be useful as an adjunct in removing organic matter. Every patient should be safeguarded by consistently high standards, because infected individuals cannot be readily identified. Prolonged periods of disinfection (at least 20 minutes) are recommended at the end of the list to reduce the risk of bacterial growth during storage and also at the beginning of lists, to remove such organisms as may have grown.

Full mechanical cleaning of the endoscope with fresh detergent before each case is the most important part of the disinfection process and should be carried out with great care. Endoscope channels (especially the air channel) must be washed free of any refluxed mucous or proteinaceous material before disinfection, otherwise solid plugs may result in blockages. Brushes and other cleaning equipment used must themselves be disinfected or sterilised before each use.

After removal from the patient the endoscope should be taken straight to the sink for washing in fresh detergent solution. It should not be placed on any other working surface.

The following recommendations all imply that cleaning/disinfection procedures will take longer than previously (10–15 minutes) and will require alternation of endoscopes during a busy list.

Three techniques are described below: the first makes full use of the immersibility of the newer equipment and will be facilitated by the use of automatic washing machines. The second is recommended for those units still using non-immersible equipment and may be used until immersible equipment is obtained. The third technique is also considered by the Working Party to be microbiologically less than ideal. It could be used with immersible equipment between cases, but only until closed disinfection systems are available and additional equipment obtained for alternation of endoscopes. This method may also be required in units where aldehyde sensitivity is a problem (despite adequate ventilation and closed systems).
and a double disinfection which includes quaternary ammonium compounds (Dettox) and alcohol is the only alternative.

The Working Party draws attention to the importance of disinfecting ancillary equipment and this, together with a section on washing machines, is detailed below.

**TREATMENT OF IMMERSIBLE ENDOSCOPES**

With the exception of highly specialised equipment nearly all endoscopes marketed are now fully immersible and have been redesigned to facilitate cleaning and disinfection. Their major advantage over earlier equipment lies not just in their immersibility, but in the ability to irrigate all channels with positive pressure. Most endoscopes have three channels: suction/biopsy, air and water. Those fitted with a bridge attachment have a fourth, smaller channel which carries the bridge elevator cable and some have a fifth injection channel as well.

It is essential to clean the equipment thoroughly with detergent before disinfection. In order to dislodge particulate matter a cleaning brush is repeatedly passed down the suction/biopsy channel and out of the tip of the instrument until clean, the brush itself being cleaned each time before withdrawal. The brush is then passed up through the suction channel in the umbilical cord. The distal hood is removed and while totally immersed, the tip of the endoscope is vigorously brushed with a soft toothbrush; valve and biopsy housings are cleaned with plastic handled cotton buds. The outside of the instrument is then washed with detergent and detergent is injected through each channel. (An all channel irrigator is supplied with some endoscopes, but a separate syringe is still needed if there is a bridge elevator channel).

The instrument is then totally immersed in an effective disinfectant which is also injected into each channel, and left to soak for four minutes. After rinsing the instrument and channels with clean water and drying it, fresh valves (suction, biopsy and air/water) and distal hood are fitted.

Except in unavoidable circumstances, adequate personnel and instruments (endoscopes and accessories) should be available so that there is no tendency to hurry the cleaning and disinfection routine, or to take short cuts. This recommended standard cycle of cleaning and disinfection with full immersion of endoscopes takes time (at least 10 to 15 minutes) and implies that two endoscopes are needed for a busy list, with additional back up equipment available in case of instrument failure. Use of automatic washing machines (see later) after initial cleaning as described above, removes some of the tedium of the routine and ensures correct timing of the wash, soak and rinse cycles.

**DISINFECTION OF NON-IMMERSIBLE ENDOSCOPES**

Non-immersible endoscopes are still in use in some units. The Working Party recommends that this type of equipment should be phased out in favour of newer immersible endoscopes. The instruments differ in construction from one another and cleaning techniques should be modified according to the manufacturers’ instructions. In practice this equipment often has ‘dead space’ in the region of the valves which may be difficult to irrigate, and the suction channel which extends from the handle of the instrument to the light source, is less accessible.
The shaft and tip of the instrument are washed in detergent, as described for immersible equipment, but the handle of the instrument and umbilical cord remains attached to the light source and must not be immersed. Detergent is sucked up the suction channel by depressing the suction valve, and squirted through the water channel from a water bottle by depressing the air/water valve. The air channel is checked to see that it is working effectively. After repeatedly passing the cleaning brush through the suction/biopsy channel and out of the tip of the instrument until clean (as for immersible instruments), a suction attachment is fitted to the biopsy valve housing and detergent is sucked through the suction/biopsy channel and biopsy valve housing by depressing the suction valve, while the tip of the instrument and suction attachment are submerged.

Disinfectant is then introduced into the water channel from a water bottle and the shaft of the instrument is immersed in disinfectant which is sucked into the suction/biopsy channel and biopsy valve housing. The endoscope is left to soak for four minutes. After thoroughly rinsing the disinfectant from the instrument and accessible channels the valves are removed. The handle of the instrument and any segment of the shaft not previously immersed in disinfectant are swabbed with 70% ethyl alcohol. All valve housings are cleaned with plastic handled cotton buds moistened with 70% ethyl alcohol and fresh valves and distal hood are fitted.

SECOND-LINE DISINFECTION METHOD FOR ALDEHYDE SENSITISED STAFF

An alternative method is detailed below for immersible instruments

The Working Party feels it is microbiologically less ideal. Total immersion of equipment in aldehyde disinfectants leads to a risk of splashing and high vapour levels. If a closed disinfection system – for example, an automatic washing machine – is not available, total immerson may be undesirable. With this technique the instrument is not fully immersed, the control body is swabbed only with 70% ethyl alcohol and there may be a greater tendency to short cuts. In addition, the procedure is, in parts, instrument specific. The Working Party considers this technique to be microbiologically less than ideal but it may be used if a closed system is not available but only until additional equipment can be obtained. In addition some units may be forced for reasons of aldehyde sensitivity to use a second line double disinfection system which includes alcohol as described earlier.

The endoscope left connected to the light source and suction, is washed in a large sink containing warm detergent solution. Detergent is sucked up the suction channel by depressing the suction valve, and squirted through the air and water channels from a water bottle by depressing the special AW channel cleaning adaptor (available with some instruments). The cleaning brush is repeatedly passed through the suction/biopsy channel and out of the tip of the instrument, until clean (cleaning the brush with each passage). A suction attachment is then fitted to the biopsy valve housing and detergent solution sucked through the suction/biopsy channel and biopsy valve housing, by depressing the suction valve, while the tip of the instrument and suction attachment are submerged. Those instruments with extra channels are flushed with detergent solution using the adaptors provided.

Disinfectant is then introduced into air and water channels from a water
bottle and the shaft of the instrument is immersed in disinfectant which is sucked into the suction/biopsy channel and biopsy valve housing. The endoscope is left for the requisite length of time. After thoroughly rinsing the disinfectant from the instrument and its channels the valves are removed. The handle of the instrument and any segment of the shaft not previously immersed are swabbed with ethyl alcohol (70%). All valves are removed and valve housings cleaned with plastic handled cotton buds moistened with ethyl alcohol and fresh valves and distal hood are fitted.

Cleaning and disinfection/sterilisation of endoscopic accessories

All ancillary equipment used during endoscopic procedures provides a potential source of transmission of microorganisms. In particular those accessory items which are designed to breach the mucosa of the gastrointestinal tract provide a portal of entry to the systemic circulation for any organisms present. Except where disposable accessories are used it is necessary between patients to clean and disinfect/sterilise accessories (including cleaning brushes and cleaning attachments) using the following procedures:

1 Wash immediately after use in fresh detergent solution.
2 Dismantle as far as possible: remove handles and withdraw inner parts where these exist – for example, remove snare wires from sheaths and inner tubes from injection needles.
3 Brush away adherent debris with cleaning brush or toothbrush.
4 Flush detergent solution through lumens of all hollow components using syringe attachments where these are available.
5 Ultrasonic clean with any lumen filled with fluid. It is almost impossible to thoroughly clean items with a spiral metal structure, such as biopsy forceps and Eder-Puestow dilatation flexible tips, without this facility.
6 Rinse thoroughly flushing lumens of hollow items well.

Then either:

7 Disinfect. Immerse equipment in the disinfectant(s) of choice with lumens filled for the required length of time.
8 Rinse thoroughly, flushing all disinfectant out of lumens.
9 Dry.
10 Lubricate all moving parts.
11 After this, equipment can be stored then redisinfected immediately before use.

Alternatively:

12 Sterilise following procedures 1–6. Accessories being stored in sterile packs which avoid the need for redisinfeciton. Methods available for sterilising accessories include:
   (a) autoclaving (where recommended by the manufacturer)
   (b) ethylene oxide gas
   (c) low temperature steam and formaldehyde.

Use of sterilisation or disposable products is particularly recommended for injection needles. A portable electric autoclave on site is practical and inexpensive. Water bottles should be disinfected or autoclaved before and after the list.
Endoscope washing machines

Endoscope washing machines of different designs are available. They do not remove the need for mechanical cleansing of the instrument to remove solid matter, including brushing the suction channels and the instrument tip. They do, however, offer several advantages:

They ensure perfusion of the air channel as well as the water/suction channels of the instrument. Optimal time cycles are automatically followed for washing/disinfection/rinsing, and the natural tendency to take short cuts during busy endoscopy lists is avoided. Nurses are therefore freed from an important, but tedious and repetitive chore. As there is no effective alternative to aldehyde disinfectants for endoscopic immersion, the use of washing machines that are plumbed in with a ‘closed circuit’ minimises staff exposure and offers a clear advantage.

Washing machines are also perceived as having disadvantages. They are relatively expensive at about £6–11 000. Against this can be set the advantages detailed above, an expected life of perhaps 10 years and the fact that the cost of a machine is similar to the cost of one endoscope. Endoscope washing machines are complex and need care in use, including appropriate periodic autodisinfecting routines to avoid any possibility of the machine itself becoming a reservoir of bacterial infection. The eight to 20 minute instrument wash cycle necessitates the use of at least two endoscopes for a busy endoscopy list. The automatic wash cycle times can be adjusted in some machines to a four minute soak time, however, with a full cycle of 10–11 minutes. These times are the same as those for ideal manual cleaning, which suggests this is an argument for adequate numbers of endoscopes rather than a valid criticism of washing machines. Finally, most washing machines are not mobile and require adequate space for installation and use.

Further experience will be needed on practical aspects of the design and use of washing machines but, given adequate finances for instrumentation (and the setting of equivalent standards of hygiene in endoscopy units to those expected in dentistry, or for minor operative procedures) the use of endoscope washing machines has much to commend it.

Facilities required for cleaning and disinfection of equipment

The present recommendations imply that many units will require extra facilities. These include an adequate space and exhaust extraction facilities such as hoods or cabinets, additional endoscopes, adequate nurse/assistant time, double sinks with running hot and cold water, disinfection trolleys/containers/washing machines, cleaning accessories (such as brushes), all channel irrigators, extra wash bottles, ventilated storage cupboards (endoscopes should not be stored in the suitcase they are supplied in), an ultrasonic cleaner, a suitable number of endoscopic accessories such as biopsy forceps, mouth guards etc., to allow for disinfection or sterilisation between use. Heat stable accessories should ideally be autoclaved. Equipment manuals and instruction sheets should be available for reference.

Protection of staff

Staff in the endoscopy room are at risk from infection which may be
transmitted from the patient and also from sensitivity to the disinfectants in use.

All staff should be offered protection against hepatitis B virus by vaccination and their antibody status should be checked following immunisation. As there is at present no vaccine available for HIV infection special precautions must be taken.

Inoculation accidents with HIV infected blood or body fluids or 'splash' injuries with blood on to skin or mucous membranes are an important but low risk to endoscopists and their assistants. In the United States of America the CDC multicentre study of needlestick or mucous membrane occupational exposure from HIV infected patients had recruited 1097 health care personnel by 31 March 1987 and in 89% of cases the accidents were needlesticks or cuts with sharp objects. Only one seroconversion has been shown. In a study at the National Institutes of Health by 30 April 1987 none of 332 workers with parenteral or mucous membrane exposure were seropositive. Similar studies at the University of California in 63 workers and the United Kingdom in 150 health care workers have not shown infection. Many accidents, perhaps thousands, have probably occurred throughout the world outside such studies and there are only seven other documented occupational exposures with seroconversion after exposure to anti-HIV positive blood. Four nurses have seroconverted after needlestick injuries: in two instances there was deep intramuscular penetration. More recently three women health care workers seroconverted after receiving splashes of infected blood on the skin and in one of these cases the oral mucous membrane. Two of the staff were not wearing gloves, in one case the hands were chapped and in the other there was dermatitis of the ear which may have been touched by a contaminated hand. The phlebotomist who received a splash in the face and the mouth, had acne, and also scratched the back of her hand two months later with a needle from an iv drug user of unknown anti-HIV status. The phlebotomist was found to be anti-HIV positive seven months after this. Two additional cases have been reported which involve people providing nursing care to persons with HIV infection, in one case a friend and in another a mother, in which both had extensive contact with blood or body fluids and neither had observed routinely recommended barrier precautions. It is noteworthy that in the needle stick studies many of the injuries were preventable. In the splash injury incidents, routine screening of all patients admitted to hospital would not have prevented the accidents, as two of the three exposures occurred in outpatients and one occurred at a resuscitation in an emergency department.

In comparison with needle stick injuries from HBV infected persons where 6–20% of health care workers have been infected, the risk after such an injury from an HIV infected patient is low.

Nevertheless the Working Party recommends that the following precautions should be taken for all patients being endoscoped, based on DHSS guidelines for identified anti-HIV positive patients. Needles should not be resheathed after use in any patient because of the risk of needle stick injury; they should be disposed of in a suitable puncture proof container. Special care must be taken with the handling of sharp instruments such as sclerotherapy needles or spiked biopsy forceps, as gloves provide no protection against inoculation injury. The routine use of spiked forceps is considered unnecessary and hazardous. Health care workers should always observe routine
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barrier precautions when in contact with blood or body fluids from any patient. Disposable liners for suction bottles are a convenient and safe method of handling endoscopic suction waste, the filled and sealed bags being sent for incineration. Open cuts, fresh abrasions, and other skin lesions, in patients and staff, should be covered with waterproof or other suitable dressings. Endoscopy staff should wear a disposable outer garment to avoid splashes on clothing, and disposable gloves and eye wash bottles should be available; goggles or glasses should be worn if eye splashes with blood are likely.

Management of the HIV infected patient

Whilst in principle the Working Party recommends an upgrading of routine practice rather than a two tier system of cleaning, disinfection, and safety precautions, it appreciates that problems will remain with the identified case of AIDS or HIV infection. The symptomatic patient with HIV infection (Stage IV CDC Classification for HIV infection) should be managed as an immunosuppressed individual. This Working Party recommends that gastrointestinal endoscopy in a symptomatic patient with HIV infection should be conducted in the same way as recommended in this document, but that it should be preceded for the protection of the patient by an immersion time of one hour in glutaraldehyde (2%), and that after endoscopy and thorough cleaning recommended in this document, the endoscope should be immersed for a further one hour in glutaraldehyde 2%, to ensure firstly that opportunistic organisms such as atypical mycobacteria are not transmitted from one immunosuppressed patient to another and secondly that M tuberculosis is not transmitted from a symptomatic patient with HIV infection to an immunocompetent patient. A dedicated endoscope is not required for this group of patients.

To protect an immunosuppressed patient it is usually recommended that the endoscope should be sterilised, that is, immersed in disinfectant for a sufficient time to inactivate bacterial spores before endoscopy (three hours in glutaraldehyde 2%, the use of diluted aldehydes require longer immersion times). In the context of gastrointestinal endoscopy, however, most bacterial spores are probably not relevant, apart from spores of Cl difficile, which are rapidly killed by glutaraldehyde 2%. With respect to cross-infection, most of the infectious complications in HIV infection are due to reactivation of latent organisms, or in some cases ubiquitous organisms, which are not pathogenic in the immunocompetent host. Two microorganisms associated with disease in the gut of HIV infected patients and which may not be inactivated by the present recommendations or cleaning and disinfection, are mycobacteria (mycobacterium tuberculosis, but more commonly atypical mycobacteria, which are ubiquitous organisms) and cryptosporidia. Longer disinfection times of up to one hour are recommended for the inactivation of mycobacteria. There is no information on the activity of common disinfectants against the intermediate forms and cysts of cryptosporidium. The inactivation times required for mycobacteria and the likelihood of their being encountered in routine bronchoscopy will inevitably lead to differences in the recommended routine disinfection times for bronchoscopic and gastrointestinal endoscopy.
Cost implications

Gastrointestinal endoscopy units should now be moving towards totally immersible equipment and more time consuming, but safer cleaning and disinfection procedures. This means that **increased funding will be necessary for capital purchases of extra endoscopes and ancillary equipment**. Busy units will require two endoscopes per list so that they can be alternated, with a backup instrument available for instrument failure, repair and overhaul. Closed systems (washing machines) for disinfection are recommended, together with better storage facilities. Endoscopy suites will need modification for better ventilation to protect staff from disinfectant sensitivity. There are in addition revenue implications. Greater numbers of properly trained GI assistants are needed for routine lists and available (if necessary as paid on call) for emergency procedures to ensure that the cleaning and disinfection recommendations and safety precautions can be scrupulously followed at endoscopy without taking short cuts.

Summary

1. All patients undergoing gastrointestinal endoscopy must be considered ‘at risk’ for HIV and appropriate cleaning/disinfection measures taken for endoscopes and accessories.
2. Thorough manual cleaning with detergent, of the instrument and its channels is the most important part of the cleaning/disinfection procedure. Without this, blood, mucus and organic material will prevent adequate penetration of disinfectant for inactivation of bacteria and viruses.
3. Aldehyde preparations (2% activated glutaraldehyde and related products) are the recommended first line antibacterial and antiviral disinfectant. A four minute soak is recommended as sufficient for inactivation of vegetative bacteria and viruses (including HIV and HBV).
4. Quaternary ammonium detergents (8% Dettox for two minutes for bacterial disinfection), followed by exposure of the endoscope shaft and channels to ethyl alcohol (70% for four minutes for viral inactivation), is an acceptable second-line disinfectant routine where staff sensitisation prevents the use of an aldehyde disinfectant.
5. Accessories, including mouthguards and cleaning brushes, require similarly careful cleaning/disinfection, before and after each use. Disposable products (especially injection needles) may be used and appropriate items can be sterilised by autoclaving and kept in sterile packs.
6. Closed circuit endoscopy washing machines have advantages in maintaining standards and avoiding staff sensitisation to disinfectants. Improved ventilation including exhaust extraction facilities may be required.
7. Endoscopy staff should receive HBV vaccination, wear gloves and appropriate protective garments, cover wounds or abrasions and avoid needlestick injuries (including spiked forceps, etc).
8. Known HIV-infected or AIDS patients are managed as immunosuppressed, and require protection from atypical mycobacteria/crypto-
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sporidia etc, by one hour aldehyde disinfection of endoscopic equipment before and after the procedure. A dedicated instrument is not required.

9 Increased funding is necessary for capital purchases of GI endoscopic equipment, including extra and immersible endoscopes with additional accessories to allow for safe practice.

10 Greater numbers of trained GI assistants are needed to ensure that cleaning/disinfection recommendations and safety precautions are followed, both during routine lists and emergency endoscopic procedures.

11 These recommendations are based on expert interpretation of current data on infectivity and disinfection; they may require future modification.

References

Cleaning and disinfection of equipment for gastrointestinal flexible endoscopy


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