

Infection control in

# Endoscopy



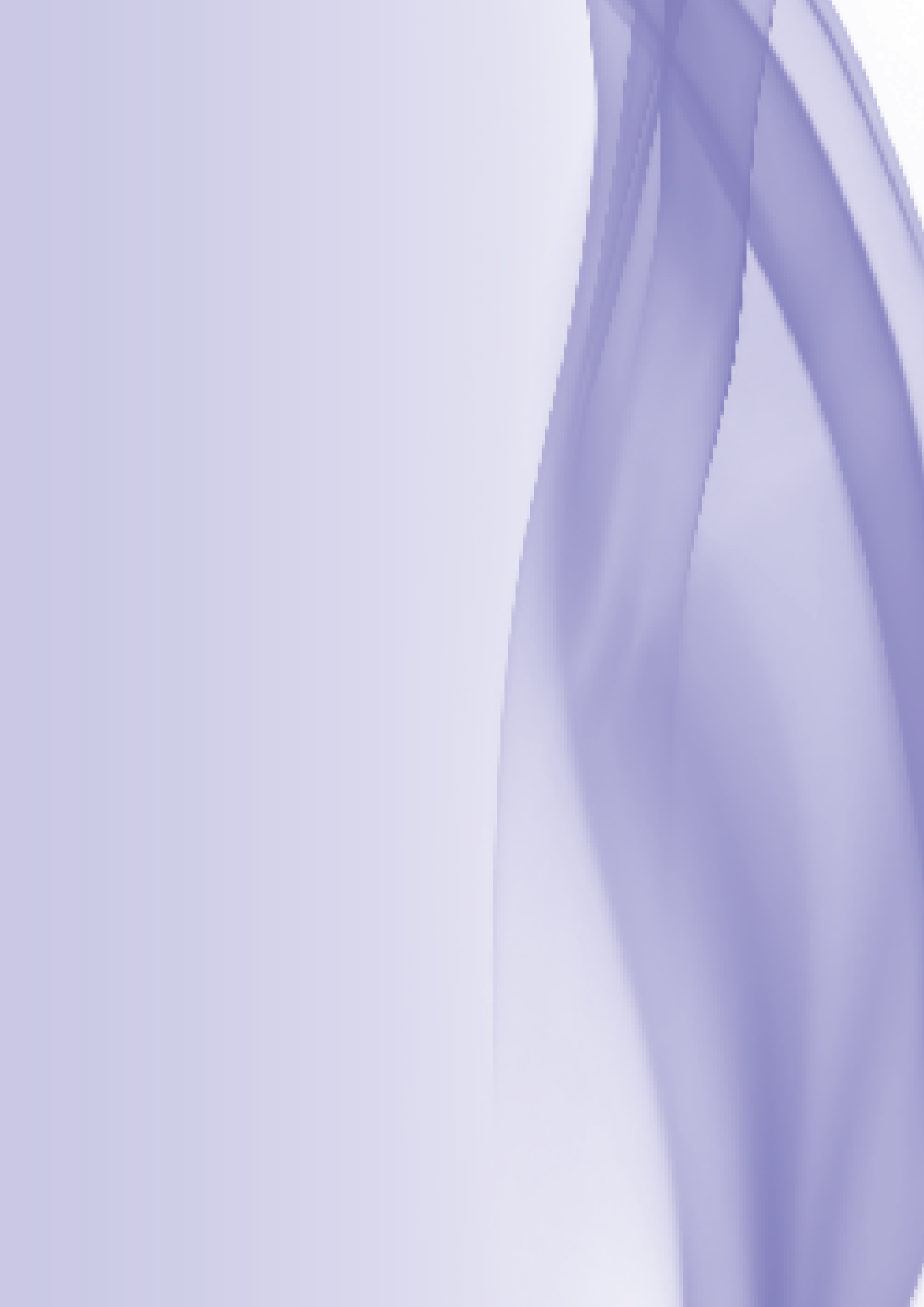
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# Introduction

## Preface

This third edition of Infection Control in Endoscopy Guidelines comes seven years after the publication of the previous edition. Not surprisingly, new research data have prompted significant changes in these guidelines, which will make a real difference to the way we manage endoscope cleaning, storage and testing in everyday practice. At this point in time, the mantra of previous editions “clean it, clean it, clean it” remains unchanged. Manual cleaning is still the cornerstone for prevention of transmission of infection in endoscopy.

The main changes in these guidelines are summarised on the next page, to help experienced staff to quickly digest the implications for their daily practice. Extending the duration that most endoscopes can be used after reprocessing to 72 hours is the most significant change, although this comes with a strong caveat that storage and testing requirements must be carefully followed.

The changes in these guidelines reflect the balanced consensus view of many and often differing opinions. Like in many areas of life and medicine, there are few black and white answers to questions in the area of infection control in endoscopy. Therefore, the expertise and constructive input of all members of this committee have been extremely valuable and appreciated.

Many thanks to all those involved in preparing this edition. Drawing input from many parts of Australia and New Zealand has been a big effort. All members of the committee have given up a significant amount of time for this project and have made a real contribution to this edition. The committee has provided an excellent balance of input from expert and dedicated nurses as well as medical specialists in infectious diseases, respiratory medicine and gastroenterology. Although Alistair Cowen relinquished the chair of this committee, his wisdom and knowledge has again been invaluable. Special thanks to Dianne Jones for shouldering a large part of the burden of this project including collating the changes and preparing the manuscript for publication.

Andrew Taylor

**Committee Chair**

## Summary of changes to this edition of the guideline

The following changes or additions have been made in this edition:

1. CJD – These guidelines have been changed to reflect the changes in the Australian Government Department of Health and Ageing Infection Control Guidelines since their publication in 2004.
2. The guidelines for antibiotic prophylaxis have been updated to reflect recommendations from various recent (and often contradictory) guidelines.
3. Endoscopic Ultrasound (EUS) endoscopes and enteroscopes have been incorporated into the current edition.
4. Gastrosopes, colonoscopes, enteroscopes and radial EUS endoscopes can be used up to 72 hours after last reprocessing provided recent microbiological surveillance cultures have been negative; duodenoscopes, bronchoscopes and linear EUS endoscopes can be used up to 12 hours after last reprocessing.
5. Emergency endoscopes e.g. intubating bronchoscopes that are not stored sterile and wrapped should be reprocessed every 72 hours even if not used. This is to ensure that in a time-critical emergency they are ready for use.
6. Due to the change in recommendations for length of storage times prior to requiring disinfection before use, it is essential that storage cupboards be tall enough to allow endoscopes to hang without touching the floor and are well ventilated, or, when endoscopes are stored horizontally, there is alarm-monitored continuous air flow through each channel.
7. Duodenoscopes, bronchoscopes, linear EUS endoscopes and Automated Flexible Endoscope Reprocessing machines (AFER) should be tested for microbial growth monthly. All other endoscopes should be tested three monthly, including those stored in a wrapped state.
8. Water supply for manual rinsing should be tested three monthly if filtered to 0.2 microns or monthly if the water is not filtered.
9. The section on AFER design and principles has been updated to reflect the ISO 15883 standards.
10. Special endoscopes no longer need to be reserved for patients with potential cCJD risk arising from gonadotrophin or growth hormone exposure.
11. Bronchoscopes do not need to be cultured for mycobacteria (except rapid-growing species, which will be detected by routine bacterial culture methods).
12. The section on loan instruments has been updated to incorporate guidance as to when they should be microbiologically tested.
13. An Automated Flexible Endoscope Reprocessor (AFER) has now been developed and marketed which uses a machine cleaning cycle to replace the manual cleaning step. This machine has TGA approval and there is published data to support its efficacy. Initial manual cleaning remains an essential step when any other AFER is used.

The three most important rules of an effective endoscope reprocessing schedule are still:

**1. Clean it**

**2. Clean it**

**3. Clean it**

## Abbreviations

<b>AFER</b>	Automatic Flexible Endoscope Reprocessor	<b>IE</b>	Infective Endocarditis
<b>AIDS</b>	Acquired Immune Deficiency Syndrome	<b>ISO</b>	International Standards Organisation
<b>AHA</b>	American Heart Association	<b>MDRTB</b>	Multi Drug-Resistant Tuberculosis
<b>AS</b>	Australian Standards	<b>MEC</b>	Minimum Effective Concentration
<b>ASGE</b>	American Society of Gastrointestinal Endoscopy	<b>NOHSC</b>	National Occupational Health and Safety Commission
<b>ATP</b>	Adenosine Triphosphate	<b>MRSA</b>	Multi-Resistant Staphylococcus Aureus
<b>BAL</b>	Broncho Alveolar Lavage	<b>MSDS</b>	Material Safety Data Sheet
<b>BBV</b>	Blood-Borne Virus	<b>NATA</b>	National Association of Testing Authorities
<b>BSG</b>	British Society of Gastroenterology	<b>NHMRC</b>	National Health and Medical Research Council
<b>cCJD</b>	Classical CJD	<b>NICE</b>	National Institute for Health and Clinical Excellence
<b>CDC</b>	Centre for Disease Control	<b>NICNAS</b>	National Industrial Chemicals Notification and Assessment Scheme
<b>CDNA</b>	Communicable Diseases Network Australia	<b>OPA</b>	<i>Ortho</i> -Phthalaldehyde
<b>CHD</b>	Congenital Heart Disease	<b>PCR</b>	Polymerase Chain Reaction
<b>CJD</b>	Creutzfeldt-Jakob Disease	<b>PEG</b>	Percutaneous Endoscopic Gastrostomy
<b>CSSD</b>	Central Sterilising Services Department	<b>PPE</b>	Personal Protective Equipment
<b>DNA</b>	Deoxyribonucleic Acid	<b>SAL</b>	Safety Assurance Level
<b>ERCP</b>	Endoscopic Retrograde Cholanigopancreatography	<b>TGA</b>	Therapeutic Goods Administration
<b>ESBL</b>	Extended-Spectrum Beta-Lactamase	<b>TSE</b>	Transmissible Spongiform Encephalopathy
<b>EUS</b>	Endoscopic Ultrasound	<b>VCJD</b>	Variant CJD
<b>FDA</b>	Food and Drug Administration	<b>VRE</b>	Vancomycin-Resistant Enterococci
<b>FFI</b>	Fatal Familial Insomnia		
<b>FNA</b>	Fine Needle Aspiration		
<b>GENCA</b>	Gastroenterological Nurses College of Australia		
<b>GESA</b>	Gastroenterological Society of Australia		
<b>GI</b>	Gastrointestinal		
<b>GSS</b>	Gerstmann-Sträussler-Scheinker		
<b>HBV</b>	Hepatitis B Virus		
<b>HCV</b>	Hepatitis C Virus		
<b>HCW</b>	Health Care Worker		
<b>HIV</b>	Human Immunodeficiency Virus		
<b>ICE</b>	Infection Control in Endoscopy		



# Sterilisation and disinfection

## Sterilisation

Sterilisation is a term describing the use of a physical or chemical procedure to destroy all microbiological life, including bacterial spores. Major sterilising processes include dry heat sterilisation, steam sterilisation under pressure, low-temperature hydrogen peroxide, plasma sterilisation, ultraviolet radiation, gamma radiation, automated peracetic acid systems and ethylene oxide gas<sup>1,2</sup>. A number of chemical germicides are capable of achieving sterilisation if used for prolonged periods. For example, to achieve sterilisation with aldehyde-based products, depending on use temperature, a contact time exceeding three hours may be required.

Any item that comes into contact with sterile body sites needs to be sterile and it would be desirable if any item (such as an endoscope) that comes into contact with an intact mucous membrane could also be sterile. At present, however, no modern flexible gastrointestinal endoscope can be regularly sterilised, either because processes such as heat and steam are incompatible with the materials of which they are composed or because processes such as ethylene oxide and prolonged chemical immersion are impractical and unlikely to achieve full sterilisation. Some models of endoscopes are marketed as capable of undergoing low-temperature hydrogen peroxide gas plasma sterilisation. This process is restricted to single lumen instruments of an inside diameter of 1mm or larger and length no longer than 850mm. In addition, the long-term effect on materials from repeated use of this process has recently been evaluated by one endoscope manufacturer after 100 cycles. The degradation of material after that period of time may necessitate an insertion tube or bending section replacement<sup>3</sup>. The recent marketing of an autoclavable flexible video bronchoscope is an exciting development. If the technology proves to be viable for other types of endoscopes, it may herald a landmark change in endoscopy practice similar to the advance made when endoscopes became fully submersible.

## Disinfection

Disinfection is not sterilisation in that it involves removing or killing the vast majority but not all micro-organisms. High-level disinfection is considered adequate for reprocessing of endoscopes because it removes or kills the

micro-organisms regarded likely to cause disease. This recommendation has not changed since Earle Spaulding devised the concept of critical (sterile), semi-critical (high-level disinfected) and non-critical (low-level disinfected) items in 1968<sup>4</sup>.

High-level disinfection processes for endoscope reprocessing need to kill all forms of bacteria (gram-positive, gram-negative and mycobacteria), viruses (both the more sensitive lipid-coated viruses such as HIV and relatively resistant viruses such as the polio virus), fungi (e.g. *Candida* spp.) and protozoa (e.g. *Giardia*) within a practicable contact time. High-level chemical disinfectants alone are able to kill the more resistant forms of microbial life such as bacterial spores and cysts but only with prolonged contact times (usually over 3 hours). Heat alone is also an effective disinfectant; for example temperatures 70°C for 100 minutes are used for pasteurisation. With high levels of wet heat and pressure (autoclaving), sterilisation is achieved. Many reprocessing systems for endoscopes use a combination of chemicals and modest heat to achieve high-level disinfection.

The ability of a disinfectant to kill all necessary micro-organisms is dependent on a number of interrelated factors:

### 1. Adequate removal of biological material

Heat and chemical disinfectants are both potentially compromised by inadequate pre-cleaning. For example, organic material binds and inactivates many chemical disinfectants and some disinfectants such as glutaraldehyde and alcohol fix protein, thereby creating a physical barrier of denatured protein that can shield micro-organisms. Obviously no agent can be effective against micro-organisms it cannot reach. An advantage of heat as a disinfecting agent is that it is conducted and therefore able to penetrate better than chemicals. The action of heat will also be compromised by inadequate cleaning, but to a lesser extent than with chemical disinfectants. If cleaning is compromised even prolonged contact time (in excess of 60 minutes) is unlikely to kill pathogenic micro-organisms present on or in the endoscope. For example, it has been shown that ten separate full disinfection cycles failed to kill *Mycobacterium tuberculosis* present in an inadequately cleaned bronchoscope<sup>5</sup>.

## 2. Initial number of micro-organisms present

The higher the number of micro-organisms present, the longer it will take to achieve a complete kill. This is another reason why cleaning is a critical step in any cleaning and disinfection protocol; a five-log or more reduction in the number of micro-organisms present can be achieved by scrupulous cleaning alone.

## 3. Temperature

In general the higher the temperature, the quicker the disinfecting agent will destroy micro-organisms. This is the basis of rapid cycles in AFERs, including machines which use glutaraldehyde, *ortho*-phthalaldehyde (OPA) or peracetic acid. For manual reprocessing, the recommended use temperature is provided on the disinfectant product label. For example, the recommended use temperature for glycolated glutaraldehyde (Aidal Plus) is 25 or 35°C and for OPA it is 20 or 25°C degrees.

## 4. Concentration

In general, the lower the concentration of the disinfectant, the longer it will take to kill the same number of micro-organisms. It is important to ensure that disinfectants do not become diluted with excess water remaining on endoscopes after rinsing – the concentration of a disinfectant may in this way be more than halved with repeated use and the efficacy of the disinfection process thereby compromised. The chemical concentration should be checked using test strips according to the recommendations on page 38.

## 5. Contact time

This is dependent on the other critical parameters of disinfectant concentration and temperature of use. Manufacturers will indicate the minimal time required for biocidal activity of their product at a specific temperature. However, these contact times are based on the endoscope being adequately cleaned beforehand.

## 6. Other factors

Successful microbial kill is also dependent on the disinfectant pH and the relative resistance (and therefore kill rate) of the micro-organism involved.

## Disinfectants for endoscope reprocessing

Agents that can achieve high-level disinfection include 2% glutaraldehyde, 0.55% OPA, peracetic acid, high concentrations of hydrogen peroxide and some chlorine releasing agents. In general, peracetic acid and high concentrations of hydrogen peroxide can only be used in automated processors that prevent staff exposure. Glutaraldehyde and OPA can be used in either manual processing or in automated processors. Ethylene oxide achieves sterilisation with prolonged contact time. However, it must be recognised that sterilisation with ethylene oxide is subject to the same limitations as liquid chemical disinfectants: sterilisation cannot be achieved in inadequately cleaned instruments.

Other chemicals such as quaternary ammonia compounds (e.g. Cetrimide) are only low-level disinfectants because they are inactive against many bacteria (e.g. *Pseudomonas* spp., mycobacteria) and have little or no activity against viruses. Alcohol and iodine, while more active than quaternary ammonia compounds, still do not kill some important pathogenic micro-organisms and are therefore not regarded as high-level disinfectants.

## Sterilisation vs high-level disinfection: the debate

Although it would be preferable to be able to sterilise each endoscope between patients, there is no evidence anywhere that patients have suffered infections with organisms that would be eliminated by a sterilising process but not by a high-level disinfection process.

Sterility is a simple theoretical concept but defining it, demonstrating it and proving its value in practice are difficult. It is impossible to test every item and batch testing of large production lines provides only some assurance. In practice, the concept of Safety Assurance Levels (SAL) is used<sup>6</sup>. A selected micro-organism (usually a bacterial spore) is tested under fixed conditions in a sterilising process and the chance of live micro-organisms remaining is extrapolated from the kill graph. The usual convention is that a device labelled as sterile has an SAL of  $10^{-6}$ . Which means that there is a less than 1 in 1 million chance that live micro-organisms remain on the device<sup>7,8</sup>. Over time there has been a progressive demand for higher SALs (up to  $10^{-8}$ ) to apply to devices labelled “sterile” but there is no evidence

of worse clinical outcomes when devices with SALs of  $10^{-3}$  are compared with SALs of  $10^{-6}$  let alone  $10^{-8}$ !<sup>9,10</sup>. Therefore, the potential clinical benefits of sterilising an endoscope rather than using high-level disinfection are very small.

There are currently many practical barriers to chemical sterilisation of endoscopes, including the potential for inadequate cleaning, staff error, mechanical endoscope defects, design flaws in AFRs and the risk of contaminated rinse water. In everyday circumstances, pathogenic bacteria may survive high-level disinfection because endoscopes develop irregularities at junctions or cracking or splitting of the surface layers of the internal channels – these defects shield micro-organisms from cleaning and disinfection. Pajkos et al examined by electron microscope 13 endoscopes submitted for servicing and found biofilm in 5 suction/biopsy channels and in 12 air/water channels<sup>11</sup>. Often, biofilms were present at sites of defects in the tubing. Buss et al<sup>12</sup> found candida contamination of damaged endoscopes. Passing “laws” or publishing standards that insist on sterile endoscopes would therefore be impossible to comply with in practice, would be deceptive to the public, expose the reprocessor to possible litigation and offer a false sense of security to the ill-informed. The realistic aim is to have a total endoscope reprocessing protocol that prevents transmission of pathogens from one patient to the next or from the hospital environment to the patient. That protocol should include microbiological surveillance of the endoscopes to identify internal damage to channels that would compromise the cleaning and disinfection process<sup>12</sup>.

Most endoscopic accessories are single-use or autoclavable if reusable. For example, because biopsy forceps breach the mucosa they should be discarded (if single-use) or sterilised<sup>13,14</sup>.

## Mechanisms of infection

### 1. Endogenous infection

Endogenous infection associated with endoscopy occurs as a result of breakdown of a normal barrier (e.g., biopsy of mucosa, entering the bronchial tree), thereby allowing the patient's own microbial flora access to a normally sterile site. This mechanism of infection is responsible for the majority of clinically important infections associated with modern endoscopy but is not related to cleaning, disinfecting or storing endoscopes<sup>15</sup>.

### 2. Exogenous infection

This guideline deals predominantly with exogenous infections associated with endoscopy – how these infections occur, how to prevent them and how to monitor the quality of the endoscope reprocessing practices. Micro-organisms causing exogenous infection arise from two sources:

1. Infective agents are transmitted from one patient to the next via the endoscope or its accessory equipment. This is most likely to occur via gastrointestinal endoscopes (historically, *Salmonella* spp.) but probably goes largely unnoticed; instead, transmission events recently most often involved bronchoscopes (e.g., tuberculosis, *Pseudomonas aeruginosa*).
2. Hospital environment pathogens may contaminate the endoscope or accessory equipment and be introduced into the patient during subsequent examination. Contamination may be from the general hospital environment, the water supply or endoscope reprocessing machines.

The overall risk of transmission of exogenous infection by endoscopy has been estimated to be 1 in 1.8 million procedures<sup>16</sup>. Infection-control failures that have been shown to cause transmissions include:

1. Failure to effectively clean the endoscope. This has been a common reason for endoscope-related transmission of infection in the past<sup>17</sup>. Nicholson<sup>5</sup> showed that a bronchoscope that had undergone ten separate complete disinfection cycles with 2% glutaraldehyde but had been poorly cleaned was still contaminated with *Mycobacterium tuberculosis*.
2. Damage to the endoscope<sup>18</sup>. Corne et al reported two clusters of pseudomonas infections and pseudo-infections related to broncho-alveolar lavage (BAL) samples collected from 16 patients. Failure to clean and disinfect two bronchoscopes occurred despite adherence to all current reprocessing procedures and this was found to be a result of damage to the biopsy channel of these endoscopes from biopsy forceps. The two outbreaks were controlled after replacing the inner channels of the bronchoscopes and switching to disposable biopsy forceps.

3. Poor endoscope design, which leads to an inability to effectively clean and disinfect the endoscope. Cêtre et al reported *Pseudomonas aeruginosa* in BAL cultures from 117 of 418 patients having bronchoscopy<sup>19</sup>. A fault was found in the bronchoscope design that led to persistent pseudomonas contamination at the entry port of the biopsy channel. Similar events occurred simultaneously in two other large centres necessitating the recall of these bronchoscopes. The issue of poor equipment design is also relevant to rigid sigmoidoscopes where there is a risk of cross contamination arising from the air insufflation bellows<sup>20</sup>, unless an in-line filter or single-use bellows are used.
4. Failure to adequately clean and disinfect accessories<sup>21,22</sup>.
5. Contaminated or faulty AFERs or their filters, especially by non-tuberculous mycobacteria, *Pseudomonas* species and related bacteria<sup>23,24,25,26,27,28,29</sup>.
6. Reuse of syringes and single-use medication vials. This has been the cause of hepatitis C transmission<sup>30,31,32</sup>. In the USA, the commonest cause of serious viral transmission associated with endoscopy is poor practice associated with intravenous sedation. The American Practitioners in Infection Control position paper on Safe Injection Infusion and Medication Vial Practices in Health Care identified that in more than 35 outbreaks of viral hepatitis occurring in the past 10 years resulted in the transmission of either hepatitis B or C to more than 500 patients<sup>33</sup>. (See the section on the relevant virus page 13.)
7. Poor compliance with guidelines is recognised in many reports of endoscope-related infection transmission<sup>34,35</sup> and is estimated to be the cause of more than 90% of reported exogenous endoscopy-related infections<sup>36</sup>. Bou et al reported a fatal outbreak of multidrug-resistant pseudomonas pneumonia in 17 patients in an intensive care setting<sup>37</sup>. The outbreak was partly attributed to several failures in reprocessing and storage of bronchoscopes in that institution, including inadequate cleaning and disinfection of the bronchoscope at weekends and a failure to correctly rinse, flush with alcohol and dry the bronchoscopes with forced air.

### 3. Pseudo-infection

Bronchoscopes are frequently used to take fluid samples (BALs) for diagnosis of lung conditions, including culture for bacteria, mycobacteria and fungi. If the bronchoscope is inadequately reprocessed or becomes contaminated for some reason then a patient sample may yield falsely positive results. Repeated positive results for the same micro-organism from BAL fluid from different patients is known as a pseudo-outbreak; there are many published examples of pseudo-outbreaks and these typically indicate a fault in bronchoscope reprocessing or the bronchoscope itself<sup>19,38,39,40,41,42</sup>. Pseudo-outbreaks may or may not be associated with clinically recognised patient infections but the contaminating micro-organism is likely to have been introduced to each patient's bronchial tree during the lavage procedure. Microbiology laboratory staff should look out for and notify to Infection Control and endoscopy staff any repeated isolation of the same micro-organism from BAL fluid culture. Pseudo-infection is occasionally also reported in association with endoscopic retrograde cholangiopancreatography (ERCP) samples.

## Infective agents transmitted by endoscopy

### 1. Bacteria

#### a) *Salmonella* and related species

Historically, salmonellae and related species have been the infections most commonly transmitted by endoscopy<sup>43,44,45,46</sup>. Many of the older reports of such infections described cleaning and disinfection regimens that would not be considered acceptable by today's standards. The majority of outbreaks were only recognised when bacteriological laboratories reported unexpectedly large clusters of infections with unusual *Salmonella* species, which led to epidemiological investigation. It is possible, therefore, that infections due to more common *Salmonella* species may have been unnoticed and under-reported. Some reports of salmonella outbreaks have been associated with inadequate cleaning of accessories, such as the failure to ultrasonically clean spiral wire wound accessories<sup>47</sup>. Increasing chemical immersion time was ineffective in at least one of these outbreaks and the problem was only terminated when proper cleaning procedures were employed.

## b) Mycobacteria

*Mycobacterium tuberculosis* and related species are relatively resistant to most chemical agents, including aldehydes<sup>48</sup>. Non-tuberculous (“atypical”) mycobacteria are even more resistant and there are reports of atypical mycobacteria that are totally resistant to glutaraldehyde<sup>49,50</sup>.

There is no proven case of transmission of tuberculosis by gastrointestinal endoscopy but there are numerous reports of mycobacterial transmission by flexible bronchoscopy<sup>21,28,29,51,52,53</sup>. Mycobacterial infections associated with bronchoscopy have been related to contaminated suction valves<sup>21</sup>, cracked biopsy channels<sup>51</sup>, contaminated topical anaesthetic solutions<sup>52</sup> and contaminated disinfecting machines<sup>28,29</sup>. Epidemics of pseudo-infection associated with contaminated disinfecting machines have also been a cause of considerable confusion<sup>54</sup>.

**The Centre for Disease Control and Prevention recommends that bronchoscopy should not be performed on patients with active tuberculosis unless absolutely necessary**<sup>55</sup>. Bronchoscopy should not be regarded as a first line investigation in the diagnosis of tuberculosis and repeated sputum smears should be negative for acid-fast bacilli before bronchoscopy is considered. Avoiding bronchoscopy in these patients is important not only from the point of view of reducing contamination of bronchoscopes for subsequent patients, but also by way of avoiding contamination of either staff or other items in the bronchoscopy suite when patients cough during or after the procedure. (See page 49 on Transmission-Based Precautions in Endoscopy Units.)

Nowhere has the critical role of cleaning been better demonstrated than with *Mycobacterium tuberculosis* and fibreoptic bronchoscopes. Nicholson<sup>5</sup> demonstrated that even extremely prolonged bronchoscope immersion in 2% glutaraldehyde will not prevent mycobacterial transmission in inadequately cleaned instruments and accessories. On the other hand, Hanson has shown in a study using bronchoscopes heavily contaminated with *Mycobacterium tuberculosis* that adequate cleaning reduced contamination by a mean of 3.5 log(10) colony forming units per ml; all bronchoscopes were subsequently free of detectable mycobacteria after ten minutes in 2% glutaraldehyde<sup>56</sup>.

Rinsing of bronchoscopes after disinfection should be with sterile or filtered water, as atypical mycobacteria are frequently present in tap water. Full air/alcohol drying at the end of lists is critical.

A further disturbing development in mycobacterial disease is the increase in multidrug-resistant tuberculosis (MDRTB)<sup>57</sup>. In this report one patient became the point source for infection of three subsequent patients: two had a benign clinical course but the third died. DNA fingerprinting proved the connection between the four patients. Note that in this outbreak the point-source patient was already heavily smear positive for acid-fast bacilli and culture positive for *Mycobacterium tuberculosis* on three sputum specimens but bronchoscopy was still done because of his worsening clinical condition despite anti-tuberculous therapy. This case reinforces the importance of avoiding bronchoscopy in either suspected or proven cases of tuberculosis wherever possible. In the outbreak Agerton et al also reported that the cleaning and disinfection of endoscopic equipment did not follow hospital or published guidelines.

The difficulty of tracing a bronchoscopic source of infection is illustrated in the report by Michele et al, who describe a patient who developed tuberculosis six months after bronchoscopy<sup>58</sup>. It was shown by DNA fingerprinting that the infection was caused by a strain of tuberculosis isolated from a patient bronchoscope two days earlier<sup>58</sup>. DNA fingerprinting was also used in the investigation of potential nosocomial transmission of tuberculosis<sup>59</sup>. Three culture-positive specimens of *M. tuberculosis* were collected with the same bronchoscope within 9 days but only 1 patient had signs and symptoms of clinical disease. The two other patients had been potentially exposed to *M. tuberculosis* from this bronchoscope.

Meticulous detailed manual cleaning by staff properly trained in bronchoscope reprocessing is the best defence against transmission of mycobacterial infection by flexible bronchoscopy.



### c) *Marcescens*

If more evidence is required of the pivotal role of adequate mechanical cleaning in endoscope reprocessing then it is provided by reports involving *marcescens*. Several outbreaks and pseudo-outbreaks of *marcescens* infection have been linked to bronchoscopy<sup>39,60,61,62</sup>. In an outbreak involving three fatalities<sup>60</sup>, the instrument had been inadequately cleaned but then subjected to a full ethylene oxide sterilising process, underlining the fact that any attempts at sterilisation or disinfection are likely to be ineffective in the presence of inadequate cleaning.

### d) *Helicobacter Pylori*

There is historical evidence that *Helicobacter pylori* was transmitted during research studies involving gastric tubes, endoscopy and biopsy, long before the micro-organism was clinically recognised (“epidemic achlorhydria”)<sup>63</sup>. *Helicobacter pylori* transmission by contaminated biopsy forceps has been demonstrated using restriction enzyme analysis of bacterial DNA<sup>64</sup>. It is probable that endoscopic transmission of *H. pylori* has been more frequent than has been recognised because of:

- i) the high background prevalence of symptoms similar to those caused by *H. pylori* infection in the population examined;
- ii) the high background prevalence of *H. pylori* infection;
- iii) the non specific nature of symptoms associated with *H. pylori*-induced gastritis; and
- iv) the frequency of asymptomatic infection.

The risk of *H. pylori* transmission from patient to patient in a modern endoscopy unit with up-to-date infection-control procedures is minimal: a recent study reported no detectable *H. pylori* DNA in samples taken from reprocessed endoscopes used on patients infected with *H. pylori*<sup>65</sup>. Another similar study reported only 1 of 128 reprocessed endoscopes with detectable *H. pylori*<sup>66</sup>. There is contradictory evidence regarding the risk of *H. pylori* infection being transmitted to endoscopy staff. No increased risk was shown in the study by Noone<sup>67</sup>. In contrast, five studies reported an increased prevalence of *H. pylori* in endoscopy staff<sup>68</sup>. Attention to basic infection control measures including hand washing remain important to minimize this risk.

### e) *Clostridium Difficile*

There are several reports of possible endoscopic transmission of *Clostridium difficile* but none has been definite. *Clostridium difficile* spores are more susceptible to a variety of chemical disinfectants than test spores used in standard analytical chemical sporicidal tests<sup>69</sup>. Exposure for 10 minutes to 2% glutaraldehyde has been shown to inactivate *C. difficile* spores<sup>70</sup>. Unfortunately, the emergence of new virulent strains of *C. difficile* suggest this will become a bigger and more difficult problem. Management of scheduling, staff protection, instrument handling and room cleaning for endoscopic procedures on known or suspected infections with new *C. difficile* strains will likely be the best defence against infection transmission.

### f) *Pseudomonas species*

*Pseudomonas aeruginosa* is a common hospital environmental pathogen and endoscope and accessory contamination with this micro-organism has most likely been acquired from the hospital environment rather than from previous patients. *Pseudomonas aeruginosa* is the archetypal biofilm-forming micro-organism (see section on biofilms). *Pseudomonas* biofilms are extremely difficult to remove from plumbing, AFERs and damaged endoscope channels.

Historically, endoscopy-associated pseudomonas infections have largely been confined to ERCP and this problem is considered in more detail under that section. Post-endoscopy bacteraemia with *Pseudomonas* species has been documented after colonoscopy and sclerotherapy<sup>71</sup> and pseudomonas septicaemia has been reported in immunocompromised patients (leukaemia, bone marrow transplantation) after upper gastrointestinal endoscopy with oropharyngeal mucositis<sup>72,73</sup>. *Pseudomonas aeruginosa* was the microbial cause of the first reported cystoscopy-associated infection outbreak, which was attributed to incorrect disinfection methods<sup>74</sup>.

*Pseudomonas* infection has recently been associated primarily with flexible bronchoscopy<sup>13,14,18,62,75,76</sup> and attributed to damaged bronchoscopes<sup>18,77</sup>, non-removal of biopsy valves, poor biopsy channel port design<sup>19</sup>, ill-fitting or incorrect AFER-endoscope connectors and defective AFERs<sup>78</sup>. The reports of the 2001 outbreak of pseudomonas infection from faulty bronchoscopes included the possible contribution to the death of three patients<sup>62,65,70,75</sup> and described the recall of approximately 14,000 bronchoscopes worldwide.

### **g) Vancomycin-resistant enterococcus and other multidrug-resistant bacteria**

Unpublished results of endoscope surveillance cultures from New Zealand show that enterococci are sometimes isolated (together with other faecal flora) from endoscopes subsequently found to have defects or faults. Although there are no reports in the literature that link the acquisition of vancomycin-resistant enterococci (VRE) to endoscopy, transmission is possible in any situation where there is a breakdown in the cleaning or disinfection process. This also applies to antibiotic-resistant enteric micro-organisms such as extended-spectrum beta-lactamase (ESBL)-producing enterobacteriaceae and non-fermentative gram-negative bacilli.

## **2. Viruses**

### **a) Human Immunodeficiency Virus (HIV)**

Infective HIV particles are present in the blood and other body fluids of infected individuals. Needlestick injury with HIV-positive blood has resulted in seroconversion in 0 to 0.42% of recipients in various studies<sup>79,80,81,82,83</sup>. The concentration of HIV in serum varies widely with the stage of the infection and use of anti-retroviral agents. HIV is sensitive to many chemical disinfectants, including aldehydes<sup>84,85,86</sup>, but if the virus is protected within a dried protein coagulum, chemical disinfectants may fail to inactivate the virus<sup>84</sup>. This emphasises the necessity to ensure that prompt and scrupulous manual cleaning removes all traces of blood and proteinaceous material from equipment. In a series of studies Hanson et al contaminated the surface and internal channels of endoscopes with high-titre HIV serum; and showed that manual cleaning alone removed HIV activity from all except a single endoscope and the remaining viral activity was removed from this endoscope after 10 minutes or less soaking in 2% glutaraldehyde. Where endoscopes were sampled after removal from HIV positive patients, all HIV present on endoscopes was removed by manual cleaning alone<sup>87,88</sup>.

To date there has been no unequivocal demonstration of transmission of HIV by gastrointestinal endoscopy. It is difficult to interpret the rare reports suggesting that some HIV material may remain on endoscopes after recommended reprocessing protocols. The PCR techniques used may identify remaining nucleic acids, which do not constitute infective viral particles. Deva et al have shown that in the Duck Hepatitis B model, positive PCR material remaining on scopes **does not** correlate with infective transmission<sup>89</sup>.

However the extremely long incubation time for clinical HIV-related symptoms or AIDS would make the detection of a very isolated instance of HIV transmission difficult.

### **b) Hepatitis B**

Hepatitis B is a highly infectious virus and high concentrations of viral particles are found in the blood of symptomatic hepatitis B sufferers and asymptomatic hepatitis B carriers, particularly those who are HBeAg-positive. Clinical hepatitis B may occur as frequently as in 1 in 3 recipients of a needlestick injury<sup>90,91,92,93,94</sup>. Despite the high infectivity of hepatitis B, there is only a single well-documented case of transmission of hepatitis B by endoscopy<sup>95</sup>. Clinical studies following up patients who have been endoscoped on the same endoscopy list as known hepatitis B-positive patients have produced no evidence of infection<sup>96,97,98,99,100,101,102,103,104</sup>. Hepatitis B virus is moderately sensitive to the majority of disinfectants<sup>105,106</sup>, but chemical inactivation requires that the germicide comes in contact with the virus and failure to remove blood, mucus and protein coagula may allow the virus to be protected from chemical inactivation.

### **c) Hepatitis C**

Human body fluids, including saliva, ascites and urine, contain significant concentrations of hepatitis C virus in infected patients. The risk of infection following needlestick injury with HCV positive blood is estimated at 3-10%, increasing with high viral loads. Several epidemiological studies link hepatitis C with gastrointestinal endoscopy<sup>107</sup>. Andrieu et al found in a hospitalised population of gastroenterology patients over the age of 45 that endoscopic biopsy was the second most powerful risk factor for hepatitis C, with an odds ratio of 2.7 compared with an odds ratio of 1.8 for blood transfusion<sup>108</sup>. Karmochkine confirmed digestive endoscopy as an independent risk factor for hepatitis C with an odds ratio of 1.9 in their group of 450 seropositive patients<sup>109</sup>. A national blood transfusion survey in France included over two and a half million blood donations and found 30 hepatitis C-positive blood donors who had made a previous donation but had screened antibody-negative. Six of 26 donors had a history of endoscopy between their negative and positive tests in the absence of any other identifiable risk factor<sup>110</sup>.

This epidemiological evidence is backed up by case studies. Tennenbaum et al reported the transmission of hepatitis C following endoscopic sphincterotomy in 1993<sup>111</sup>. Bronowicki et al reported hepatitis C transmission during colonoscopy from a known infective patient to the two subsequent patients on the list<sup>112</sup>; the cause of endoscopic transmission is likely to have been an inadequate cleaning protocol, including failure to brush the biopsy channel, or inadequate processing of the biopsy forceps or polypectomy snare. Transmission of hepatitis C during gastroscopy has also been reported by Crenn et al<sup>113</sup>. Single-strand conformational polymorphism analysis of the hypervariable region of HCV RNA confirmed the patient-to-patient transmission. It is claimed that adequate reprocessing protocols were followed for the endoscope but it is unclear in this case whether the anaesthetic procedure or the endoscope was the cause of the transmission.

Becheur et al have shown that hepatitis C virus is detectable by PCR in 28% of endoscope biopsy channels and on 6% of biopsy forceps after use in patients with non-treated replicative chronic hepatitis C<sup>114</sup>. They found that conventional reprocessing techniques removed all viral material. In contrast to some of the above studies, Goudin et al in Lyon, France, tested for hepatitis C infection in all patients referred for endoscopy and could find no definite evidence of transmission and only one possible case<sup>115</sup>.

Proven transmissions of hepatitis C by an endoscope remain confined to France. It is unlikely that this geographical restriction will continue. There are very few studies from elsewhere in the world that have prospectively examined endoscopy as a risk factor for hepatitis C transmission. A study by Kim et al from Korea did not identify endoscopy as a significant risk factor<sup>116</sup>. In Northern Italy, endoscopy was not associated with hepatitis C infection<sup>117</sup>. In all reports except one there have been deficiencies in endoscope and accessory reprocessing. This is not altogether surprising since Raymond in 1990 found that 73% of all units surveyed in France had protocol deficiencies<sup>118</sup>. This, however, should not lead to any sense of complacency elsewhere. Reynold's survey in the USA in 1992 showed that 40% of units surveyed had inadequacy in some aspects of their protocols<sup>35</sup>. There are no recent Australian surveys, but past surveys were little better and there is recent anecdotal evidence that the very protocol failures associated with transmission of hepatitis C at colonoscopy had been present until recently in a small number of Australian endoscopy units.

At present the evidence indicates that cleaning and disinfection protocols, when properly applied

during endoscope and accessory reprocessing, will render instruments and accessories free of the risk of transmission of hepatitis C<sup>119</sup>. A recent review of blood-borne virus transmission by endoscopy concluded that the risk was very low even when the endoscope was inadequately cleaned or disinfected<sup>120</sup>.

Transmission of hepatitis C has recently occurred in endoscopy suites, however, from breakdowns in practice not directly associated with the endoscope. For example, 14 cases of hepatitis C appear to have been transmitted at a Brooklyn endoscopy clinic because of reuse of syringes or needles<sup>30,121</sup>. In another report, 71 cases of hepatitis C and 31 cases of hepatitis B infection appear to have been transmitted by a similar mechanism in an Oklahoma day surgery pain remediation clinic<sup>31</sup>. The investigation in 2008 into an outbreak of hepatitis C in Southern Nevada showed transmission likely resulted from reuse of syringes and single-use medication vials on multiple patients in an endoscopy clinic and led to 40,000 patients being notified of their potential risk for exposure to hepatitis C and other blood-borne pathogens<sup>32</sup>. In a report in 2010, 12 persons acquired HBV and HCV infections (six hepatitis C, five hepatitis B, and one coinfection) in two separate sites as a result of receiving anaesthesia for outpatient endoscopy procedures<sup>122</sup>. The anaesthetist involved in both endoscopy units re-used syringes to re-dose patients from a single-use propofol vial that was then used on subsequent patients. The CDC Epidemic Intelligence Officer who investigated these multiple clusters has urged gastroenterologists to carefully review the injection, medication handling and other infection control practices of all staff under their supervision, including anaesthesia services. A report of 2 cases in Australia, 1 of whom underwent colonoscopy, also identified contaminated anaesthetic ampoules as the source of contamination<sup>123</sup>.

It is vital for prevention of blood-borne virus transmission that the following recommendations are followed:

1. Never use needles **or syringes** on more than one patient.
2. Never use drug infusion sets on more than one patient. Changing the delivery tubing but reusing the medication container is **NOT** acceptable.
3. Using a new needle but a used syringe to draw up further medication from a multi-dose vial is **NOT** acceptable.
4. If using a multidose vial, all doses of the medication should be drawn up from the vial into separate syringes **BEFORE** the list commences.



Finally, accessory equipment used in endoscopy procedures has also been considered a potential source of nosocomial infection. In 2009, over 10,000 patients from Veterans Administration hospitals in 3 states in the USA were screened for blood-borne virus infections following the recognition of the use of an incorrect valve for water pumps attached to colonoscopes. The incorrect valve did not prevent back flow from the endoscope channel into the water pump reservoir. Ten patients have proven positive for hepatitis C and 2 for HIV. It is not known whether those infections were acquired during endoscopy<sup>124</sup>.

#### d) Enteroviruses

Polioviruses are more resistant to many chemical disinfectants than the viruses that have a high lipid content (e.g. HIV). Hanson et al studied the elimination of enteroviruses from endoscopes by artificially contaminating endoscopes with high levels of polio virus and subjecting them to standard cleaning and disinfection protocols<sup>125</sup>. The effectiveness of glutaraldehyde against cell-free and cell-associated polio viruses dried to a surface in a protein coagulum was studied. Cleaning and disinfection were totally effective against a heavy viral contamination and glutaraldehyde rapidly inactivated polio virus even when dried to a surface in serum.

### 3. Other infections

A wide variety of other bacteria, viruses, fungi and protozoa could potentially be transmitted by endoscopy. Candida infection of immunocompromised patients has been linked to upper gastrointestinal endoscopy<sup>126</sup>, and an epidemic of pseudo-infection with the yeast *Rhodotorula rubra* has been reported in bronchoscopy patients<sup>127</sup>.

The sensitivity of many unusual micro-organisms to chemical disinfectants is largely unknown. However some agents such as the oocysts of cryptosporidia are highly resistant to a variety of chemical disinfectants including 2% glutaraldehyde<sup>128,129</sup>. It is unlikely that such micro-organisms pose a significant threat to patients with normal immune systems; however they could be responsible for serious and even fatal infections in the immunocompromised.

La Scola et al have raised the possibility of transmitting Whipple's disease (*Tropheryma whipplei*) by endoscopy and duodenal biopsy<sup>130</sup>. In their testing, chemical disinfection with either glutaraldehyde or peracetic acid did not result in a 5-log reduction of *T. whipplei*. It had been presumed that *T. whipplei*, which

is phylogenetically related to mycobacteria, would have been killed by high-level disinfection so further studies are needed to confirm this reduced susceptibility to disinfectants.

#### Creutzfeldt-Jakob disease and other transmissible Spongiform Encephalopathies (TSE's)

Transmissible spongiform encephalopathies (TSEs) have now been shown to occur in many mammalian species. They represent a group of degenerative central nervous system disorders caused by a unique pathogen called a prion. Unlike conventional pathogens, prions contain no nucleic acid and are therefore resistant to conventional forms of sterilisation used in healthcare settings. Specific infection-control guidelines have been developed to prevent the nosocomial transmission of these agents between patients and between patients and staff.

Classical Creutzfeldt-Jakob Disease (cCJD) is the most common TSE but is a rare disorder, occurring sporadically at a rate of about 1 case per 1,000,000 population. Even more rare are the other human TSE's including Gerstmann-Sträussler-Scheinker syndrome (GSS) and Fatal Familial Insomnia (FFI). For the purposes of infection control, these diseases are included in the terminology cCJD (classical CJD), which must be distinguished from the variant form of CJD (vCJD) described in the UK and Europe over the past decade and believed linked to the use of animal products in ruminant feeds. Variant CJD differs in clinical presentation and age of onset from cCJD and most importantly also in the distribution of prions within the body of an infected person. In cCJD, infective prions are confined to tissues and secretions of the central nervous system; in vCJD, prions are found in lymphoid tissue and potentially in blood (at least four cases in the UK have been linked to blood transfusion). Because of these variances, potential routes of infectivity are different and therefore different infection-control guidelines are applied to patients who have or may have these disorders. Variant CJD has not been described in Australia or New Zealand and for this reason Infection Control Guidelines recommended in endoscopy are focussed on cCJD<sup>131</sup>. In the event of a patient with possible vCJD requiring endoscopy, expert advice must be obtained and can be sought from the Department of Pathology, Royal Melbourne Hospital from whom the names of expert members in each State of the National CJD Incident Group can be obtained to provide a local perspective to advice.

The National Infection Control Guidelines on transmissible spongiform encephalopathies in Australia have classified the infectivity of various tissues in patients with cCJD and also divided patients into a tripartite risk classification<sup>131</sup>.

## 1. Tissue risk classification

Infectivity category	Tissues
High	Brain
	Dura mater
	Pituitary gland
	Spinal cord
	Retina
	Optic nerve
	Cranial and dorsal root ganglia
	Olfactory epithelium*

\*Normal nasal endoscopy procedures do not reach the olfactory epithelium.

## 2. Patient risk classification

1. High-risk patients are those known or suspected to have cCJD following presentation with neurological symptoms.
2. Low-risk patients are those who are neurologically well but have potentially acquired cCJD through exposure to gonadotrophins or growth hormone suspected of being contaminated with cCJD prion proteins or who have been part of a "look-back study" following possible prion protein exposure during medical procedures.
3. Background-risk patients (i.e. no increased risk for cCJD over other members of the community).

By combining these two risk classifications, a matrix to indicate appropriate infection control guidelines in any patient undergoing endoscopy has been developed. This matrix determines when it is necessary to apply additional precautions over and above recommended Standard (routine) Precautions for endoscopic procedures.

## 3. Recommended precautions

Patient-risk categories	High-infectivity tissue exposed	Low-infectivity tissue exposed
<b>High-risk</b> Patients with a <b>definite</b> risk of cCJD infection (generally showing neurological symptoms)	Additional precautions required	Standard Precautions
<b>Low-risk</b> Patients who represent a <b>potential</b> risk of cCJD infection (have an identified risk factor)	Additional precautions required	Standard Precautions
<b>Background-risk</b> The general population who have no identified increased risk of cCJD infection.	Standard Precautions	Standard Precautions

IMPORTANT NOTE: Because none of the tissues exposed during naso-endoscopy, bronchoscopy or gastrointestinal endoscopy are classified as more than low-infectivity, no respiratory or gastrointestinal endoscopic procedure, (even in patients who are themselves classified as high-risk) requires the application of more than Standard Precautions (i.e. endoscopes can be processed in the same way as those for patients with background risk of cCJD). Special endoscopes no longer need to be reserved for patients with potential cCJD risk arising from gonadotrophin or growth hormone exposure.

# Risks of infection after endoscopic procedures and recommendations for antibiotic prophylaxis

## Introduction

Transient bacteraemia has been detected frequently after various types of endoscopy but clinical infections are rare. The exceptions to this statement are peristomal infections complicating percutaneous endoscopic gastrostomy<sup>132</sup> and post-ERCP cholangitis<sup>133</sup>. Antibiotic prophylaxis has been widely used but clinical data supporting its effectiveness outside of percutaneous endoscopic gastrostomy (PEG) and ERCP procedures are lacking. Recent guidelines have consequently recommended fewer indications for prophylactic antibiotics, especially those indications that relate to prevention of endocarditis. In this chapter, the patient risk factors for infection are discussed, including the risks with specific forms of endoscopy and current recommendations for prophylaxis. Bronchoscopy is discussed separately at the end of the chapter.

## Patient and procedure-related factors associated with a risk of endoscopy-associated bacteraemia and infection

### 1. Compromised immune status

There is some evidence that impaired immune status increases the risk of endoscopy-associated infection, although other papers have not shown an increased risk. For example, one case series report of profoundly immunocompromised individuals undergoing upper gastrointestinal endoscopy after bone-marrow transplantation described a high rate of clinically significant bacteraemia<sup>134</sup>, but two subsequent studies did not confirm this<sup>135,136</sup>. Concern was also raised after two early case reports described serious bacteraemia complicating colonoscopy and biopsy in cirrhotic patients<sup>137,138</sup>, but no clinically significant infections have been reported in more recent case series of colonoscopy in cirrhotic patients, with or without ascites<sup>139,140</sup>. There are no data on endoscopy-associated infection risk in individuals with other forms of immunosuppression, such as organ transplant recipients or HIV-infected individuals. Endoscopists may consider prophylactic antibiotics for patients with very compromised immune status, especially when there are other risk factors for infection.

### 2. Intrinsic sources of infection

In situations where an endoscopic procedure involves instrumentation of an infected site, the infection may be aggravated and bacteraemia induced. ERCP in the setting of cholangitis, and colonoscopy in diverticulitis are the most common examples. Antibiotic therapy to cover potential infecting micro-organisms is indicated.

### 3. Increased risk of bacterial lodgement during bacteraemia

Any abnormality of the endovascular surface is susceptible to bacterial lodgement during bacteraemia. This applies especially to prosthetic or severely damaged heart valves<sup>141</sup>, and less commonly to other endovascular implants such as recently inserted stents, filters, pacemakers, defibrillators and long-term venous access devices<sup>142</sup>. Foreign materials within the body but not in the intravascular space, such as prosthetic joints, are also at risk of bacterial lodgement, although the risk appears to be low. The evidence relating infections of these sites to endoscopy is presented below.

### 4. Procedure induced tissue damage

The incidence of bacteraemia following endoscopy appears to correlate with the amount of tissue damage and disruption during the procedure. For example, variceal sclerotherapy (10-50%), oesophageal dilatation (30-50%) and oesophageal laser therapy (35%) have much higher rates of bacteraemia than diagnostic upper or lower endoscopy (2-4%)<sup>141</sup>, and are likely to lead to higher risks of clinical infection especially in those with other risk factors. Therefore, endoscopists should consider the likely magnitude of tissue damage when deciding whether to give antibiotic prophylaxis in an individual case.

## Frequency and significance of bacteraemia following gastrointestinal endoscopy

### 1. Incidence of bacteraemia with GI endoscopy and other activities

Many studies have been designed to determine the incidence of bacteraemia after GI endoscopy by taking blood cultures at a series of time intervals following the procedure. These studies have shown bacteraemia after most forms of GI endoscopy, with the highest risk procedures being oesophageal dilatation and laser therapy, variceal sclerotherapy and ERCP in a setting of unrelieved biliary obstruction. These studies have been summarised in review articles that are tabulated on the next page.

## Approximate incidence of bacteraemia in immunocompetent individuals undergoing gastrointestinal endoscopy

Procedure	BSG review (%) bacteraemia rate <sup>143</sup>	Nelson Et Al % bacteraemia rate <sup>144</sup>
Rectal digital examination	4	
Rigid sigmoidoscopy	5 – 9	7.6
Barium enema	11	
Tooth brushing	25	
Dental extraction	3 – 60	
Colonoscopy	2 – 4	4.4
Diagnostic gastroscopy +/- biopsy	4	4.1
Flexible sigmoidoscopy		0.5
ERCP (no duct occlusion)	6	6.4
ERCP (duct occluded)	11	18
Variceal band ligation	6	8.8
Sclerotherapy	10 –50	14.6
Oesophageal dilatation/prosthesis	34-54	
Oesophageal laser therapy	35	
EUS + FNA	0-6	0

Table reproduced from BSG guidelines on antibiotic prophylaxis in gastrointestinal endoscopy<sup>141</sup>.

## 2. Significance of bacteraemia

Although bacteraemia following GI endoscopy has been extensively studied, the actual risk of clinical infection has not been adequately assessed in large prospective studies. In addition, even when an infection occurs some time after GI endoscopy, it is difficult to prove a direct link with the endoscopic procedure. Therefore, the degree of risk of clinical infections following GI endoscopy remains uncertain, and consequently conclusions of expert panels over many years have varied widely. It seems logical that bacteraemia occurring in the setting of patient risk factors such as abnormal vascular surfaces or immunosuppression could lead to clinical infection and, as discussed below, clinical infections have been reported following GI endoscopy. The most serious potential sequelae of bacteraemia include infective endocarditis, meningitis, cerebral abscess, and infected ascites in patients with cirrhosis. These complications, whilst rare, are theoretically more likely to follow procedures associated with the highest risk of bacteraemia, such as oesophageal dilatation or

injection sclerotherapy of varices. The specific micro-organisms cultured after endoscopy are often common causes of important infections, such as infective endocarditis. In one study of bacteraemia following oesophageal dilation, *Streptococcus viridans* was the micro-organism isolated in 79% of cases<sup>145</sup>. Micro-organisms commonly cultured after colonoscopy include *Enterococcus*, other gram-negative bacilli and anaerobes, which are potentially important pathogens<sup>146,147,148,149</sup>.

The arguments against bacteraemia associated with endoscopic procedures being significant are that (i) bacteraemia occurs more frequently after a regular daily activity such as tooth brushing than after most forms of endoscopy<sup>141</sup>, (ii) clinical infections appear to be rare, based on the relatively small numbers of case reports as a proportion to the massive numbers of endoscopic procedures carried out and (iii) most positive cultures after gastrointestinal procedures are transient and also of low density<sup>146</sup>.

## Association of gastrointestinal endoscopy with clinical infections

### 1. Infective endocarditis

There are 23 case reports implicating endoscopic procedures as a cause of bacteraemia leading to infective endocarditis, which were summarised by the authors of the 2009 British Society of Gastroenterology (BSG) guidelines on antibiotic prophylaxis in gastrointestinal endoscopy<sup>141</sup>. These comprised six individuals with no valve disease known, six with prosthetic valves and 11 with mitral or aortic valve disease of various sorts including mitral valve prolapse. These cases occurred after both upper endoscopy (12 patients, including two after sclerotherapy and three after oesophageal dilatation) and lower endoscopy (11 patients). Endocarditis occurred within weeks of the procedures although there was marked variation in the interval. Infecting micro-organisms were mainly viridans-group *Streptococci* in those associated with upper GI endoscopy and *Enterococcus* species following lower GI endoscopy. Despite these cases, some authorities are sceptical that there is a true causal link. For example, the authors of the 2008 American Society of Gastrointestinal Endoscopy (ASGE) guidelines state that “there are no data that demonstrate a causal link between endoscopic procedures and infective endocarditis”<sup>150</sup>. Evidence in support of this view is: (i) in none of 17 series of post-endoscopy bacteraemia reviewed by the authors of the National Institute for Health and Clinical Excellence (NICE) guidelines was bacteraemia followed by endocarditis or clinically significant infection evident<sup>151</sup>. (ii) In the only published case-control analysis on this subject, there was no statistically significant link with recent upper or lower GI endoscopy in 273 individuals who developed endocarditis. However, there was a trend towards an association with recent upper (2.9 vs 1.5%) and lower endoscopy (5.1 vs 2.9%). Additionally, there was a statistically significant association with recent barium enema and diagnosis of infective endocarditis<sup>152</sup>.

### 2. Infected joint prostheses

Septic arthritis of prosthetic joints can be a catastrophic event and therefore many clinicians recommend prophylactic antibiotics because of a theoretical risk of bacterial seeding following GI endoscopy, especially within 6 months of implantation<sup>153</sup>. The actual risk appears to be low as there are only two case reports of septic arthritis of prosthetic joints associated with endoscopic procedures<sup>154,155</sup>.

### 3. Infections of vascular grafts and other nonvalvular cardiovascular devices

There are no case reports directly implicating endoscopy as a cause of infection of non-valvular vascular grafts and devices, including stents, pacemakers, filters and defibrillators. In 2003, the American Heart Association (AHA) stated that there was no evidence that micro-organisms associated with GI endoscopic procedures cause infection of such devices at any time after implantation<sup>142</sup>.

### 4. Infections related to PEG

The passage of the inevitably contaminated end of the gastrostomy appliance through the mouth, stomach and abdominal wall creates a substantial risk of local infection around the insertion site, with clinically important wound infection rates between 19% and 32% reported<sup>156,157,158,159,160</sup>. The risk of infection is highest in patients with cancer, following insertion of large-bore tubes and when the procedure is undertaken in certain institutions or by inexperienced endoscopists<sup>161</sup>.

### 5. Infections associated with ERCP

ERCP has the highest rate of serious infective complications of any GI endoscopic procedure, with cholangitis and sepsis reported in 0.3 to 5% of cases and less commonly liver abscess, acute cholecystitis, infected pancreatic pseudocyst and infection following duodenal perforation<sup>162,163,164,165,166</sup>. The main risk factor for biliary infection following ERCP is failure to relieve obstruction of the biliary system. In one study, incomplete biliary drainage was present in 91% of cases of sepsis<sup>167</sup>.



Several cases and outbreaks of cholangitis and septicaemia following ERCP due to *Pseudomonas* spp. and similar bacteria such as *Proteus* spp. were reported in the 1980's and early 1990's. These micro-organisms colonise damp surfaces. The usual source of *Pseudomonas aeruginosa* has been the channels within the endoscope itself, although occasionally contamination of accessory equipment has been responsible. The major causes of infection that have been traced as a result of single clinical cases of infection or mini epidemics have included: (i) inadequate disinfection of the endoscope with particular faults being related to inadequate cleaning and disinfection of the forceps raising channel<sup>168,169</sup> (ii) failure to rinse the channels at the end of the post-session cleaning and disinfection process with alcohol and to subsequently dry the channels with forced air<sup>168,170</sup> (iii) contamination of the water feed system and water<sup>170,171</sup>, and (iv) contamination of disinfecting machines by *Pseudomonas* spp. (See section on endoscope washing machines - see page 35). It is essential that cleaning and monitoring procedures for endoscopes and cleaning machines are carefully followed to avoid repeats of these outbreaks. It is important to note that such outbreaks are not just of historical interest. A prospective study of clinical sepsis in 2067 consecutive ERCPs performed in 2002-2003 found a sepsis rate of 1.5% with a mortality rate of 26% in these patients. Ten of 30 patients with identified bacterial causes had infections with *Pseudomonas*, *Klebsiella* and *Enterobacter* species, which were felt to be exogenously introduced, presumably due to deficiencies in the endoscope cleaning process<sup>172</sup>.

## 6. Infections with EUS-FNA

Research data from two large series of EUS-FNA of a variety of lesions, both solid and cystic, showed only three infective complications from 672 procedures<sup>173,174</sup>. The risk with FNA-EUS of cystic lesions appears to be higher, with a 14% rate of clinical infection reported in one small series<sup>175</sup>.

## Evidence of effectiveness of antibiotic prophylaxis with GI endoscopy and recommendations for antibiotic prophylaxis

Guidelines on the use of prophylactic antibiotics with GI endoscopy have radically changed with the publication of a succession of updated guidelines over the last two years, initially from the AHA and NICE and subsequently from the ASGE and BSG<sup>141,150,151,176</sup>. All of these influential guidelines now recommend against giving antibiotics for

prophylaxis of infectious endocarditis, even in those with high-risk cardiac lesions and endoscopic procedures, whereas previous versions of guidelines from these organisations recommended prophylactic antibiotics for patients with high-risk cardiac lesions undergoing procedures with a high to moderate likelihood of causing bacteraemia. It is important to note that these changes are not the result of influential new evidence, but on new interpretation of the evidence, with a greater emphasis on recommendations that are based on direct evidence, even in situations where there is a deficiency of evidence either way.

The arguments for and against the use of prophylactic antibiotics and the recommendations of other recent authors or groups are presented below.

## 1. Infective Endocarditis (IE) prophylaxis. Rationale for and against antibiotic use for IE prophylaxis

All the major published guidelines now recommend that patients undergoing GI-tract procedures should not be given antibiotics solely to prevent IE. The new recommendations are based on the following lines of rationale<sup>141,150,151,176</sup>:

- i) Cases of IE associated with GI procedures are anecdotal.
- ii) No data demonstrate a conclusive link between GI procedures and the development of IE. The single published case control study did not show a statistically significant link between prior GI endoscopy and IE<sup>152</sup>.
- iii) Bacteraemia is more commonly detected after daily activities such as tooth brushing than by endoscopy.
- iv) No data exist that demonstrate that antibiotic prophylaxis prevents IE after GI-tract procedures. There are reports of IE occurring despite antibiotic prophylaxis.
- v) Only an extremely small number of cases of IE may be prevented, even if antibiotic prophylaxis is 100% effective.
- vi) There is a small risk of anaphylaxis or *C. difficile* infection due to antibiotics.
- vii) Even if antibiotics prevent some cases of IE, this intervention may not be cost effective.

The arguments for antibiotics use for IE prophylaxis in high-risk individuals are:

- i) Endocarditis usually follows bacteraemia.
- ii) Bacteraemia is well documented following GI endoscopy.

- iii) There are case reports of IE following GI endoscopy.
- iv) Although rare, IE can be a catastrophic event when it does occur.
- v) Individuals with underlying cardiac risk factors for IE can usually be identified.
- vi) The relevant bacteria are usually sensitive to readily available antibiotics.
- vii) Antibiotics have been shown to reduce bacteraemia rates after endoscopy. A randomised study showed bacteraemia in 0/132 individuals given antibiotics compared to 13/132 controls<sup>177</sup>.
- viii) There is some evidence that antibiotic administration during dental or surgical procedures reduces the risk of endocarditis<sup>135</sup>. In a rabbit model, antibiotic prophylaxis reduced the risk of infection in damaged valves following high bacterial challenge<sup>178</sup>. A retrospective case-control study of patients at risk suggested that antibiotic prophylaxis reduced the rate of IE in dental practice<sup>179</sup>.
- ix) The risk of serious side-effects of antibiotics is small. The incidence of anaphylaxis after penicillin allergy is approximately 1/5000<sup>180</sup>.

The AHA guidelines identify who is likely to have poor outcomes if they develop IE:

1. Patients with a prosthetic cardiac valve.
2. Patients with a history of previous IE.
3. Cardiac transplant recipients who develop cardiac valvulopathy.
4. Patients with unrepaired congenital heart disease (CHD) or repaired within 6 months.

Current AHA guidelines recommend prophylactic antibiotics for these individuals when undergoing some dental procedures, but not for GI endoscopy. For patients with these cardiac conditions who have established infections of the GI tract in which enterococci may be part of the infecting bacterial flora, the AHA suggests that the antibiotic regimen include an agent active against enterococci (ampicillin, amoxicillin, vancomycin or teicoplanin), especially when an endoscopic procedure is undertaken into the infected site, which may increase the likelihood of bacteraemia. An example of this is ERCP in the setting of cholangitis<sup>176</sup>.

## 2. Joint prosthesis infection prophylaxis

Current published guidelines do not recommend antibiotic prophylaxis for individuals with prosthetic joints undergoing endoscopy though some authors advise their use within 6 months of prosthesis insertion<sup>141,150,151,176</sup>. In a 1997 survey of infectious disease clinicians, there was an equal recommendation for and against antibiotics for a patient undergoing colonic polypectomy within 6 months of a prosthesis insertion<sup>153</sup>. The American Association of Orthopaedic Surgeons advocates antibiotics for all patients with joint prostheses undergoing endoscopic procedures that could produce bacteraemia<sup>181</sup>.

## 3. Prophylaxis against infections of vascular grafts and other nonvalvular cardiovascular devices

Antibiotic prophylaxis before GI endoscopic procedures is not recommended for patients with synthetic vascular grafts or other nonvalvular cardiovascular devices<sup>141,150,151,176</sup>.

## 4. Prophylaxis against PEG-related wound infection

Meta-analysis (including randomised controlled trials of first and second generation cephalosporin and amoxicillin/clavulanate) has demonstrated that antibiotic prophylaxis dramatically reduces the risk of peristomal infection (OR 0.35)<sup>132</sup>. The 2008 ASGE guidelines recommend the routine use of an antibiotic such as cefazolin 1g IV 30 minutes before the procedure<sup>150</sup>. Such agents are active against common skin pathogens, a range of gram-negative enteric bacilli and most oropharyngeal flora. Many patients who receive PEG tubes have medical co-morbidity (e.g., cancer, diabetes) and a history of hospitalisation, both of which both increase the risk of oropharyngeal colonisation with resistant gram-negative bacilli and *Staphylococcus aureus* (including MRSA). Pre-insertion oropharyngeal swabs yielding *S. aureus*, *Pseudomonas aeruginosa* or *Candida* spp. have been found to correlate with post-insertion exit-site infections with these micro-organisms<sup>160</sup> and some authors recommend pre-insertion nasopharyngeal or oropharyngeal swabbing of high-risk patients to guide additional targeted prophylactic antibiotics<sup>182</sup>, though ASGE and BSG guidelines do not include this recommendation<sup>141,150</sup>.

## 5. Prophylactic antibiotics with ERCP to prevent biliary infections at ERCP

Although in the meta-analysis by Harris et al the benefit of pre-ERCP antibiotic prophylaxis on bacteraemia and sepsis/cholangitis did not reach statistical significance<sup>183</sup>, the use of such antibiotics is widespread and we agree with recent recommendations that prophylactic antibiotics should be given before the procedure to those at highest risk of post-ERCP infection<sup>150</sup>. This includes those with:

- i) Biliary tract obstruction involving the hilum or sclerosing cholangitis.
- ii) Pancreatic necrosis, pseudocysts or cysts.

If biliary obstruction cannot be completely relieved during the procedure then prophylactic antibiotics should be started immediately and consideration given to continuing antibiotics for an additional few days after the procedure. Patients with pre-existing features of biliary or pancreatic infection should be started on antibiotics before ERCP. There are few data to guide the choice of antibiotic for prophylaxis at the time of ERCP. The common pathogenic micro-organisms encountered in the biliary tree are *Pseudomonas aeruginosa*, *Klebsiella* spp., *E. coli*, *Bacteroides* spp. and *Enterococci*. Optimum benefit of antibiotics will only be obtained if therapeutic levels are present in the bile and tissues at the time of examination. Patients should commence antibiotic prophylaxis intravenously at least one hour before the procedure. Based on recent studies of post-ERCP bacteraemia, knowledge of the common causes of intra-abdominal sepsis, randomised trials of cephalosporins and pharmacokinetics of various agents, the options include oral or intravenous amoxicillin/clavulanate, oral ciprofloxacin, an intravenous cephalosporin or intravenous gentamicin (+/- amoxicillin). The BSG guidelines advocate ciprofloxacin 750 mg orally 60–90 min before procedure or gentamicin 1.5 mg/kg intravenously<sup>141</sup>. In situations where cover against *Enterococci* is desired, ampicillin, vancomycin or teicoplanin should be added. This especially applies to prevention of endocarditis (see above)<sup>150</sup>.

## 6. Prophylactic antibiotics for EUS-FNA

The ASGE and BSG guidelines recommend giving prophylactic antibiotics prior to EUS-FNA of cystic lesions, but not solid lesions. Either ciprofloxacin or amoxicillin/clavulanic acid are recommended<sup>141,150</sup>. ASGE recommends continuing antibiotic cover for three days after EUS-FNA of cystic lesions.

## 7. Prophylactic antibiotics for neutropenic and immunocompromised patients

Although there are no direct data on the benefit of antibiotic prophylaxis in immunocompromised patients undergoing endoscopy, there is some evidence of increased risk of sepsis following endoscopy in severely neutropenic patients. The ASGE guidelines make no recommendation in this situation but the BSG guidelines recommend that patients with a neutrophil count below  $0.5 \times 10^9/l$  should be offered antibiotic prophylaxis for those gastrointestinal endoscopic procedures that are known to be associated with a high risk of bacteraemia<sup>141</sup>. Gram-negative aerobic (and less frequently anaerobic) bacteria, including *E. coli*, are the most likely pathogens in these conditions, and the choice of prophylactic antibiotics should reflect the local susceptibilities of these bacteria. There are no data to guide a decision on antibiotic prophylaxis in less severely immunocompromised individuals and published guidelines do not recommend antibiotics<sup>141,150</sup>.

## 8. Antibiotics in cirrhotic patients with GI bleeding

Although not strictly related to endoscopy, the endoscopist will often be in a position to institute antibiotic treatment to cirrhotic patients with GI bleeding. A meta-analysis of eight trials has shown a significant beneficial effect of antibiotic prophylaxis in reducing bacterial infections and mortality in patients with cirrhosis who develop GI bleeding<sup>184</sup>. Antibiotic therapy with intravenous ceftriaxone has been shown to be superior to norfloxacin and should be started on admission<sup>150,185</sup>.



## Summary of ASGE, BSG and AHA guidelines

### 1. Situations in which antibiotics are recommended by ASGE, BSG and AHA (where relevant) guidelines are:

- a) Treatment of active infections such as diverticulitis or cholangitis. Antibiotics should cover *Enterococci* if there are high risk cardiac factors for endocarditis.
- b) PEG.
- c) ERCP with unrelieved obstruction.
- d) EUS-FNA of cystic lesions.
- e) GI bleeding in cirrhotic patients.

### 2. Situations in which antibiotics are not recommended by ASGE, BSG and AHA (where relevant) are:

- a) Prophylaxis specifically for infective endocarditis.
- b) Prophylaxis for infection of non-cardiac vascular grafts and devices including pacemakers, stents and filters.
- c) Prophylaxis for infection of joint prostheses.

### 3. Situations in which there are differences in recommendations by ASGE, AHA and BSG guidelines are:

- a) Endoscopy in severely neutropaenic patients is recommended by BSG guidelines.
- b) There are some differences in the specific antibiotics recommended.

## Recommendation

The authors of this publication recommend that clinicians apply their own clinical judgement in the application of these guidelines in clinical practice. In particular, we believe there is room for clinician choice in the use or non-use of antibiotics for prophylaxis of IE in individuals with high risk cardiac lesions and recent prosthetic joint implants undergoing endoscopic procedures causing a high risk of bacteraemia. The arguments for and against antibiotic use in these situations are presented above. The potential risks and benefits of treatment and non-treatment need to be weighed up in each patient.

## Antibiotics used in prophylaxis

### 1. Ampicillin and amoxicillin

Ampicillin and amoxicillin are effective against gram-positive bacteria, including streptococci and most enterococci, which cause most infective endocarditis. These antibiotics are the first choice in situations where antibiotics are for IE prophylaxis.

### 2. Aminoglycosides

Aminoglycosides such as gentamicin increase the bactericidal activity of ampicillin or amoxicillin against streptococci and enterococci. Gentamicin is also active against most gram-negative bacteria, including most *Pseudomonas* spp. Although the risk of nephrotoxicity or ototoxicity is negligible with only one or two doses, care must be taken in patients with a history of pre-existing renal impairment.

### 3. Quinolones

Ciprofloxacin has good activity against aerobic gram-negative bacteria and therefore is widely used for the prevention of cholangitis with ERCP. It is much less active against gram-positive species, including *Enterococci*, and is therefore not suitable for prevention of endocarditis. Oral ciprofloxacin is recommended for patients in whom it can be taken as it is as effective but cheaper than the intravenous preparation.

### 4. Glycopeptides

Glycopeptides such as vancomycin or teicoplanin have a broad spectrum of activity against gram-positive bacteria. Their major role is to cover streptococcal and enterococcal infection in patients with recent exposure to penicillin, ampicillin or amoxicillin, and in individuals who are allergic to penicillins. Teicoplanin has the advantages over vancomycin of simpler and quicker administration and more sustained blood levels after a single dose. Vancomycin-resistant enterococci (VRE) are being encountered with increasing frequency in some hospitals and some strains retain susceptibility to teicoplanin. Teicoplanin is more expensive than vancomycin and the improved pharmacokinetics are not of any advantage if the post-procedure bacteraemia is likely to be transient.

### 5. Other beta-lactam agents

Cephalosporins have no activity against enterococci, but do have a broad spectrum of activity against gram-negative bacilli (especially third-generation cephalosporins such as ceftriaxone). Ureidopenicillins, such as piperacillin, are also broad-spectrum agents but with limited activity against most strains of *C. difficile*. Like cephalosporins, they may provoke *C. difficile* infection.

Scenario for prophylaxis	Rationale	Recommendation	Antibiotic options
High risk cardiac lesion undergoing endoscopic procedures with high risk of bacteraemia (see discussion on previous pages)	Infective endocarditis prophylaxis	Not routinely recommended	
		Reasonable to consider antibiotics in individual patients after weighing risks and benefits	Ampicillin or Vancomycin or Teicoplanin if allergic to penicillin
Clinical infection in or adjacent to region of endoscopy: e.g. diverticulitis with colonoscopy or cholangitis with ERCP	Prevention of procedure-related bacteraemia	Recommended	Appropriate antibiotics to cover common organisms (see discussion above and Australian Antibiotic Guidelines)
	Treatment of infection	Recommended	Ampicillin or vancomycin or teicoplanin if allergic to penicillin
	Prophylaxis of infective endocarditis where high-risk cardiac factors coexist	Recommended	
PEG placement	Prevention of peristomal infection	Recommended	Cefazolin 1g IV 30 minutes before the procedure or Amoxicillin/clavulanic acid 1.2g IV prior to procedure (or orally 1h prior) or Ticarcillin/clavulanic acid 3.1g IV
ERCP with removal of stones or straight-forward stent placement	Prevention of cholangitis	Not recommended	
ERCP with unresolved obstruction	Prevention of cholangitis	Recommended	Ciprofloxacin 750 mg orally 60–90 min before procedure or gentamicin 1.5 mg/kg IV
ERCP with biliary tract obstruction involving the hilum or sclerosing cholangitis	Prevention of cholangitis	Recommended	As above
ERCP in setting of pancreatic necrosis, pseudocysts or cysts with connection to PD	Prevention of cholangitis	Recommended	As above
			Other antibiotics may be chosen (see discussion on previous pages)
EUS-FNA of solid lesion	Prevention of local infection	Not recommended	
EUS-FNA of cystic lesion	Prevention of cyst infection	Recommended	Ciprofloxacin 750mg orally or Amoxicillin/clavulanic acid 1.2 g IV (or orally 1h prior) Or Ticarcillin/clavulanic acid 3.1g IV
Severe immune-suppression (neutrophil count $< 0.5 \times 10^9/l$ ) and high-risk procedure (see discussion on previous pages)	Prevention of bacterial sepsis	Recommended	Cephazolin 1g (adult $\geq 80$ kg: 2g) (child: 25mg/kg up to 1g) IV
Patient with cirrhosis and upper GI bleeding	Prevention of infections such as bacterial peritonitis	Recommended	Ceftriaxone 1g IV or gentamicin 2 mg/kg IV given immediately before the procedure Discuss with haematologist and/or ID physician
Patients with vascular grafts and other non-valvular cardiovascular devices	Prevention of graft infection	Not recommended	
Joint prosthesis	Prevention of infection of joint prosthesis	Not routinely recommended	
		Some clinicians recommend antibiotic prophylaxis within 6 months of placement of prosthesis. Reasonable to consider antibiotics in individual patients after weighing risks and benefits.	

# Principles of effective decontamination protocols

## 1. Introduction

**The most important step in the process of endoscope decontamination is scrupulous manual cleaning prior to disinfection.**

Viruses and bacteria can persist for long periods on surfaces, especially in the presence of biological material<sup>186</sup>. Manual cleaning refers to the physical task, performed by hand, of removing biological material from the endoscope with appropriate brushes, cloths, detergents and water. It should not be confused with mechanised cleaning, whereby a cleaning process is performed by a machine, or mechanised disinfection, whereby a cleaned endoscope is placed in a machine that disinfects and rinses the instrument. An endoscope reprocessing machine that performs mechanised cleaning has been developed and has demonstrated an equivalent level of efficacy for removal of biofilm and micro-organisms as optimal manual cleaning<sup>187</sup>. Ultimately machines with mechanised cleaning are likely to replace manual cleaning if their efficacy can be validated by independent studies and if they achieve the support of the relevant Australasian federal agencies and wider scientific and endoscopy community.

In order for manual cleaning to be effective it must:

1. Be performed by a person conversant with the structure of the endoscope and trained in cleaning techniques;
2. Be undertaken **immediately** after the endoscope is used so that biological material does not dry and harden;
3. Follow a protocol that, using appropriate detergents and cleaning equipment, allows all surfaces of the endoscope, internal and external, to be cleaned;
4. Be followed by thorough rinsing to ensure that all debris and detergents are removed prior to disinfection.

## 2. Effectiveness of recommended protocols

Hanson et al showed that recommended protocols removed all microbiological contamination from endoscopes used to examine patients with HIV and HBV infection<sup>87,88</sup>. They also confirmed that endoscopes artificially contaminated with serum containing high titres of these viruses have all microbiological activity removed by appropriate reprocessing. These results have been confirmed by a number of other studies, including that of Chu et al who quantitated the dramatic reduction in bacterial contamination by cleaning of colonoscopes<sup>188</sup>; Gillespie et al who found only 6 positive surveillance cultures out of 2374 collected over a 5-year period in their Melbourne endoscopy unit<sup>189</sup>; and Deva et al<sup>190</sup>, who made three critical findings:

1. When followed meticulously, recommended reprocessing protocols removed microbiological contamination.
2. That bacterial contamination was an accurate index of viral contamination.
3. That even minor deviations from cleaning protocols resulted in persistent microbiological contamination after disinfection<sup>190</sup>.

Not all investigators have been able to confirm such satisfactory results after recommended reprocessing<sup>191,192,193,194,195</sup>, but the amount of residual contamination in these studies has generally been small. Unfortunately, even when reprocessing appears to be following current guidelines, unexpected breakdowns in infection control can occur and lead to patient infections. These breakdowns can occur for a diverse variety of reasons, such as unseen endoscope damage<sup>196,197</sup>, disinfectant-resistant micro-organisms<sup>198</sup>, or incorrect detergent concentration<sup>199</sup>. This supports the need for additional testing of endoscope reprocessing by surveillance culture (see section Quality control – page 37). **It also emphasises that present reprocessing techniques are less than ideal and have a lower margin of safety than is desirable, reinforcing the need for all steps in the reprocessing protocol to be carried out meticulously.**

A standard for testing of cleaning efficiency in endoscope manual reprocessing protocols has not yet been developed, although several studies have examined methods such as adenosine triphosphate (ATP) bioluminescence in an endeavour to provide a marker of cleanliness<sup>200</sup>. The determination of cleaning efficacy of automated flexible washer-disinfectors (AFERs) has been studied and the standard is now prescribed in ISO 15883-1<sup>201, 202</sup>.

### 3. Endoscope structure

There are multiple different models of flexible endoscopes available in Australia and NZ. An instruction book is supplied with each endoscope by the manufacturer. It is essential that every person responsible for endoscope decontamination reads these instruction books and is familiar with the particular characteristics of each model of endoscope they are required to clean. This is of particular importance when reprocessing loan endoscopes, which may be a different model or have been modified.

#### Common external features

All flexible endoscopes have a light guide plug, an umbilical cable (cord), a control head and an insertion tube.

##### a) The light guide plug

The light guide plug connects into the light source. The air/water and suction channels have ports in the light guide plug.

The light guide plug of a video endoscope is larger and heavier than that of a fibrescope. The terminals in the light guide plug are not waterproof and must be covered by the soaking cap supplied with the instrument prior to cleaning. Periodical checks should be made to ascertain continuing watertightness of these caps.

##### b) The umbilical cable/universal cord

The umbilical cable connects the light guide plug to the body of the endoscope. The external surface may be contaminated by splashes or hand contact during endoscopic procedures.

##### c) The control head

The control head contains the angulation control handles, which allow the operator to flex the instrument, and suction and air/water valves for control of air and water flow from the distal tip. Fibreoptic endoscopes have an eyepiece on the control head. Video endoscopes are similar in construction to fibreoptic endoscopes, except that they do not have an eyepiece - the image is seen on a video screen. The control head is contaminated during endoscopic procedures by the operator's hands. The control handles have grooved surfaces, which must be carefully brushed during cleaning. The hollow structure of some control handles should be noted and care taken to ensure that the undersurface is thoroughly rinsed and emptied of fluids. The seats, which house the suction and air/water valves (buttons), must be thoroughly cleaned with appropriate brushes. The biopsy channel port is located at the base of the control handle near its junction with the insertion tube. This port must be brushed carefully during the cleaning process.

##### d) The insertion tube

The insertion tube enters the patient's body and is grossly contaminated during the procedure. The distal tip of the insertion tube houses the microchip in video endoscopes, the openings for the suction, air/water and jet washing channels and the lens covering the flexible fibreoptic light guides. The section of the insertion tube adjacent to the distal tip is known as the bending section. The outer covering is made from soft flexible material and is particularly vulnerable to damage especially if handled carelessly.

#### Common internal features

The suction and air/water channels and the fibreoptic light guide extend from the light guide plug to the distal tip. In non-video models, an additional fibreoptic bundle, the image guide, extends from the control head to the distal tip. The cables, which allow the tip to be flexed, run through the insertion tube. Any damage to either the umbilical cable or the insertion tube can potentially damage any of the internal structures. Care must be taken during cleaning procedures to ensure that the umbilical cable and insertion tube do not become kinked or acutely bent. Kinks in the biopsy channels trap debris and lead to failure of the cleaning process. Suspected damage should be referred to the supplier for assessment and repair. A negative leakage test does **NOT** exclude damage to internal endoscope structures.

### Special internal features

Most duodenoscopes have an additional channel - the forceps elevator (raiser), which is extremely fine (capacity 1 to 2 mls) and requires scrupulous attention during the cleaning process. Cleaning adaptors for this channel are provided with each duodenoscope/therapeutic endoscope and must be used.

Some colonoscopes are configured with a carbon dioxide channel (CO<sub>2</sub>) connected to the air channel instead of connection via the water bottle. In that instance, cleaning protocols should include individual flushing of this channel.

Flushing (jet washing) channels are found in many endoscopes. These are grossly contaminated during procedures and must be independently flushed during cleaning whether or not they have been used.

Balloon channels are found in enteroscopes and ultrasound instruments, cleaning protocols should include individual flushing of this channel.

## 4. Cleaning equipment

All endoscopes are supplied with appropriate cleaning adaptors that provide access for cleaning and disinfection fluids to the internal channels of the endoscope. It is vital that persons cleaning endoscopes are familiar with these adaptors and use them correctly. "O" rings on the adaptors must be inspected regularly for defects or looseness and should be replaced as required. Substitute cleaning equipment should not be used unless approved in writing, by the supplier of the instrument as the flow volumes through channels cannot be guaranteed.

Cleaning brushes of an appropriate size are required for endoscope channels and valve ports. Reusable brushes have a limited life; they should be inspected regularly and replaced when worn or kinked. Single-use brushes are available. Metal wear from abrasion by cleaning brushes and other endoscope accessories may occur on the edge of the biopsy valve or suction button ports. Alternatives to bristle brushes have been developed and demonstrated efficacy of cleaning. These include bladed cleaners and a novel product that involves microballs containing minute fibres being aspirated through the channels. The bladed cleaner was shown to achieve equal cleaning efficiency with one pass of the cleaner vs four passes of a bristle brush<sup>203</sup>. The microballs showed significantly greater efficiency in removal of bacteria and equivalence for protein removal when compared to bristle brush cleaning<sup>204</sup>.

Soft toothbrushes are useful to clean grooved control handles and to brush the distal tip and biopsy ports. Cotton buds may be used to clean the biopsy valve caps but should not be used in the air/water port as threads may become caught and cause blocked channels. Single-use biopsy valves are available.

Adequate supplies of disposable cloths should be available.

## 5. Cleaning fluids

Detergents assist in wetting of and penetration into soil and in containment of the removed material in suspension. Enzymes digest biological material, enhancing removal by brushing and flushing. These products reduce micro-organism load by up to 3-fold<sup>205</sup>.

Enzymatic detergents should be used at the correct temperature and concentration<sup>199</sup>. Manufacturers of enzymatic solutions report optimum efficacy when the products are used in warm water (35°C). However, enzymes will continue to be active when the solution has cooled to room temperature (20°C). Conversely, the use of hot water (>60°C) denatures proteins and inactivates enzymes, whilst heavy contamination may exceed the enzyme's activity capacity. The Cheetham study also highlighted the importance of enzyme stability during storage, with significant negative effects on both amylase and protease activity in some products from storage<sup>205</sup>.

The use of enzymatic detergents may pose a workplace safety hazard. Occupational asthma and other allergies have been documented with the use of proteolytic enzymes in the manufacture of detergents<sup>206</sup>, and there have been anecdotal reports of possible allergic reactions in staff using enzymatic detergents in the reprocessing of endoscopes. Enzyme-free products are available. These biofilm detachment agents are now a widely used alternative cleaning product<sup>207,208</sup>.

## 6. Biofilm

Many bacteria are capable of only existing in a planktonic state (free suspension). Other bacteria, including *Pseudomonas* species, *Legionella* species and atypical mycobacteria have the ability to exist either in a planktonic state or to form biofilms. Biofilm is formed when these bacteria adhere to a surface and secrete large amounts of polysaccharide to form a protective matrix or film around themselves. These biofilms protect the bacteria against physical (e.g., brushing, fluid flow) and chemical (e.g., disinfectant) forces, making the micro-organisms more difficult to remove or destroy. Biofilms are relevant for endoscope reprocessing in several ways:

- a) Biofilms are known to exist in municipal and hospital water pipes, especially old or altered “dead-run” pipes. This can lead to chronically contaminated water being delivered to the endoscopy suite. Filter banks are generally used to prevent this contaminated water from reaching AFERs but these filters themselves may rapidly clog or develop biofilms and require repeated applications of oxidising agents or hot water to remain effective. Iron fragments in old plumbing can also damage these filters. Sometimes a multi-disciplinary task force including engineers, water filtration experts, clinical microbiologists and endoscopy staff is required to resolve hospital water supply and filter problems (see Rinsing water).
- b) Biofilms can become established in endoscopes despite recommended cleaning and high-level disinfection protocols, especially at sites of defects in the endoscope tubing<sup>209</sup>. Biofilms can also become established in AFERs and getting rid of them may occasionally require major rebuilding of the machine.
- c) Biofilms that develop in endoscopes and AFERs may not be detectable by surveillance culture, as bacteria within the superficial layers may have been destroyed by cleaning and disinfection but those within the deeper layers have not<sup>210</sup>. Thus to identify bacteria growing from biofilm, sampling for microbiological surveillance cultures should be performed after storage of at least 12 hours following disinfection.

Agents that specifically act to break down biofilms are now often used for routine endoscope reprocessing<sup>207,208</sup>.

## 7. Rinsing water

If an instrument has undergone a “sterilising process” and is rinsed in water that is not sterile or if the sterility of the water has not been validated, then it is clearly wrong and misleading to claim that the instrument is sterile<sup>211,212</sup>.

If an instrument that has undergone a high-level disinfection process is rinsed with water that is not of high-level disinfection quality or if the water quality has not been validated, then it is clearly wrong and misleading to claim that the instrument has achieved high-level disinfection.

A number of endoscopy-related outbreaks and pseudo-outbreaks have been caused by contamination of AFER rinse water and a recent survey in the UK showed that the majority of endoscopy units were not able to achieve an acceptable quality of rinse water<sup>213</sup>. The final rinse water for bronchoscopes and duodenoscopes should be bacteria-free and it is desirable that the final rinse water for other endoscopes should also be of high quality and free of bacteria known to cause invasive clinical disease, including *Pseudomonas* species<sup>24,214,215</sup>. The water used after manual cleaning and before disinfection does not need to be bacteria-free.

Water quality (see also Biofilms on this page) is a whole-hospital issue and not simply an endoscopy-unit problem<sup>216,217,218,219,220,221,222</sup>. The endoscopy unit must insist that water delivered to the unit is of acceptable quality. Endoscopy unit water management efforts can become an expensive and ineffective waste of time if the wider problems are not addressed.

Even when water delivered to the endoscopy unit is of acceptable quality, many problems can still occur. All endoscopy units should have an isolation system, with an access point at the beginning of the water delivery and an access point immediately prior to the entry into the AFERs. The water line between these two points should include filter banks and, if necessary, other water-processing systems. The filter banks are often in a 3- or 4-stage filter size arrangement from 10 micron to 0.2 micron absolute final filter. This isolation loop must be easily and preferably automatically accessible to the particular water processing system used. Many individual systems have been used<sup>223</sup>, these include biofilm removal by oxidising agents or glutaraldehyde, line and filter sterilisation by physical agents such as hot water<sup>224</sup>, chemicals such as chlorine-releasing agents, reverse membrane osmosis, ultraviolet irradiation and Sterilox systems. The chosen method must be compatible with the filters, some of which can resist certain chemicals but not others, some



can be backwashed, some cannot, etc. Choosing and maintaining your local system must be a multidisciplinary approach with involvement of hospital engineers, AFER representatives, filter manufacturers, clinical microbiologists, infection control officers and endoscopy unit personnel<sup>225,226,227</sup>.

No system is foolproof and water quality delivered to the AFER should be monitored by bacterial culture if cultures taken from the machine outlet are positive.

## 8. Manual rinsing

Failure to rinse away the enzymatic detergent has been found to affect the amount of residual OPA and proteinaceous material on the endoscopes<sup>228</sup>. Failure to adequately rinse glutaraldehyde from endoscopes has been reported to cause severe post-colonoscopy colitis and may be responsible for some cases of post-ERCP pancreatitis<sup>229</sup>. Residual OPA stains protein and has been reported to stain patients' lips following upper gastrointestinal endoscopy and cause aerodigestive tract chemical burn injury when used for intraoperative transoesophageal echocardiography<sup>230</sup>.

Rinsing should take place under cold running water; rinsing in bowls of water is not effective in removing chemical residue. The amount of water required to thoroughly manually rinse an endoscope after disinfection will vary according to the design and length of the instrument; the manufacturer's instructions for volume of rinse water should be followed. It is unlikely that volumes of less than 150 ml in each channel will be effective in removing glutaraldehyde residue and unlikely that volumes of less than 250 ml in each channel will be effective in removing OPA residue<sup>231</sup>.

## 9. Disinfectants

Disinfectants for use in endoscope reprocessing are regulated by the Therapeutic Goods Administration (TGA)<sup>232</sup>. Only those chemicals approved for use and listed on the Australian Register for Therapeutic Goods may be used to reprocess endoscopes. Worldwide, glutaraldehyde is the chemical disinfectant most frequently used in manual disinfection systems either as 2% alkaline glutaraldehyde (e.g. Cidex) or 2% neutral complexed glutaraldehyde (e.g. Aidal Plus) formulations. OPA is also used in manual systems. In addition, glutaraldehyde and OPA in different formulations and peracetic acid are used in machine systems in Australia and New Zealand.

Chemical manufacturers are regulated to provide disinfectant contact times on the product label. The recommended contact time will differ if the disinfectant temperature or concentration is higher, and product labels will give a range of times based on the other parameters. At room temperature (20°C) soaking times of 10-20 minutes for glutaraldehyde and OPA in manual systems are usual. AFERs are licensed for use with a particular chemical used within specific parameters. Products are not interchangeable, thus manufacturer instructions must be followed regarding product use with individual machines.

Endoscopy should only be performed in centres where adequate facilities for safe cleaning and disinfection are available. For example, chemical disinfection must take place in an area with forced air extraction extending to the rinsing sink. Soaking bowls must have close fitting occlusive lids. Post-disinfection rinsing should be performed in cold running water as warm or hot water increases the amount of chemical vapours generated. Staff required to chemically disinfect endoscopes must be provided with education in the safe use of the disinfectant and with personal protective clothing that includes impervious gowns or aprons, gloves that have been approved for use with the chemicals used and face shields (see Workplace Health and Safety - page 48).

## 10. General maintenance

Leak testing of endoscopes should be performed after each use, prior to immersion in fluid, as per manufacturers' instructions. Removal of control buttons will assist in detection of minor leaks arising from cracks in a channel. Flexing of the distal tip whilst the instrument is pressurised will assist in detection of leaks in the "A" rubber of the bending section. Failure to detect a leak prior to thorough cleaning and disinfection may result in major internal damage to the instrument.

Examination of the instrument lens and outer sheath should be performed following each session to detect any signs of cracking or damage. The function of angulation cables should be checked.

Inspection of "O" rings on valves for sign of wear should be performed at the end of each session; these "O" rings should be replaced if signs of wear are detected. Biopsy caps should be checked for signs of wear and replaced as required.

## 11. Lubrication

Lubrication is used to ensure optimal functioning of both endoscopes and accessories. The “O” rings on some brands of suction and air/water control buttons require lubrication to prevent the buttons sticking in the depressed position. Traditionally silicone oil supplied with the endoscope has been used. Silicone oils can be either petroleum-based or in a water-soluble base. There is evidence that both preparations may impair reprocessing<sup>233,234</sup>. Biological fluid can be trapped within oil globules and protected from disinfectant action. The choice is therefore to either take particular pains to ensure complete removal of silicone-based lubricants or to use surgical instrument lubricant.

### Recommendations

- a) Accessory items processed in ultrasonic cleaners should be lubricated with an instrument lubricant following completion of the ultrasonic cleaning. They should then be wiped with a clean, lint-free cloth and allowed to air dry prior to packaging for steam sterilisation.
- b) If silicone oil lubricants are permitted by the manufacturer to be used for suction and air/water control buttons, they should be applied immediately before use (**after** chemical disinfection or sterilisation). It is essential to remove lubricant residue to allow germicide contact. Ultrasonic cleaning will remove any small remaining amounts of lubricant.

## 12. Work areas

Work areas should be planned and organised carefully to ensure staff safety and to protect reprocessed endoscopes from re-contamination or damage. Work flow should be from dirty to clean with segregation of the areas if possible. The cleaning area should include the following:

1. At least one sink designated for the cleaning of instruments, referred to as the “dirty” sink. This should be made of materials that are impervious to fluid, such as stainless steel, porcelain or a plastic-bonded material. The sink must be of sufficient dimensions to adequately hold a coiled full-length colonoscope without causing the instrument damage. The sink should be supplied with hot and cold running water.
2. An area adjacent to this sink where the components of the instrument are removed for cleaning. The “dirty” bench is then suitable for holding instruments awaiting chemical disinfection.
3. An area for disinfection of instruments. In the case of automated reprocessors the dimensions and requirements are dictated by the make and model of the machine(s) to be installed. For manual disinfection, a sink or container designed for liquid-chemical disinfection and of sufficient dimensions to hold an instrument without damage to the instrument is required. It is preferable that this container be fixed and placed under an appropriate fume-extraction system.
4. Where an automated disinfectant is used, rinsing is performed within the machine. Where manual rinsing occurs, a sink designated for rinsing only clean instruments must be available and contained within the fume extraction system.
5. A “clean” area for reassembly of the disinfected endoscope and its accessories ready for use or for final handling prior to storage.

Ventilation of the endoscopy suite is an important consideration for procedure, reprocessing and recovery areas. In addition to the targeted fume extraction requirements for the reprocessing area if manual disinfection is used, the endoscopy suite needs good ventilation to minimise staff inhalation of biological aerosols. For reprocessing areas, a minimum of 10 air exchanges per hour is required (AS4187)<sup>235</sup>. The 1997 American Institute of Architects Guidelines for Design and Construction of Hospital and Health Care Facilities states the minimum number of air changes per hour for an endoscopy room should be six; for hospital sites with chemicals there is a higher recommended minimum number of air changes per hour. Other references suggest ventilation rates in disinfection areas ranging from 7 to 15 air changes per hour<sup>236,237</sup>.



# Decontamination regimens

## 1. Manual cleaning

### Pre cleaning

The following steps should be performed immediately following a procedure. Bronchoscopes do not have air/water channels but should otherwise be processed according to these steps.

- 1.1 **IMMEDIATELY** after each procedure with the endoscope still attached to the light source, grasp the control head. Using a disposable cloth soaked in detergent solution, wipe the insertion tube from the control head to the distal tip. Discard cloth.
- 1.2 Place distal tip in detergent solution (see page 27). Aspirate through suction channel - depress and release suction button rapidly to promote debris dislodgement. Alternately suction cleaning fluid and air by raising the instrument tip in and out of the cleaning solution. Continue aspiration until clean fluid is seen.
- 1.3 Depress and release air/water button several times to flush water channel. Occlude air button to force air through the air channel.
- 1.4 Depending on the brand of endoscope, either (1) insert the special air/water channel feed button and depress the button to flush with water then release for air flow to expel the water; OR (2) move the lever on the water feed connector to close off the water supply, then depress the water feed button until water is expelled; OR (3) disconnect the water bottle connector from the endoscope taking care not to contaminate its end, then occlude water connector port on the light guide plug and depress the water feed button until all water is expelled.
- 1.5 The endoscope should be removed from the light source and taken to the cleaning area. Endoscopes should be transported in a manner that avoids environmental contamination from drips or spills. Ensure protective caps are applied before immersing in solutions. (If due to local circumstances there is a delay prior to thorough cleaning, first leak test the instrument then submerge the endoscope in a container of detergent solution and soak). It is essential that the endoscope is not allowed to dry prior to cleaning as this will allow organic material to dry, making removal from channels difficult or impossible. It should be noted that to be compliant with T.G.A. registration, reprocessing of endoscopes in the new cleaner-disinfector AFER must be

commenced within one hour of the procedure. Endoscopes should never be left soaking for long periods e.g. overnight.

### Leak testing

- 1.6 Remove all valves and buttons prior to leak testing. Leak test the instrument as per manufacturer's instructions.

### Cleaning

To avoid omission of steps in the cleaning process, one person should perform the full manual cleaning of an instrument. If a change in personnel occurs during the cleaning of a single instrument then the process should be recommenced.

- 1.7 Make up detergent solution (page 27) as per manufacturer's instructions. Detergent solution should not be reused,
- 1.8 Brush and clean buttons and valves paying particular attention to internal surfaces. Place buttons in an ultrasonic cleaner.
- 1.9 Place endoscope in detergent solution and wash all outer surfaces. Discard cloth after use.
- 1.10 Brush all sections of the suction/biopsy channel and air/water channels if the instrument design allows. Some twin-channel instruments will require brushes of differing sizes. If the brush contains obvious debris it should be cleaned before being withdrawn. Some brushes are designed to be used in one direction as a pull-through instead of withdrawing the brush. Each channel should be brushed until all visible debris is removed.
- 1.11 Using a soft brush, gently clean the distal tip of the endoscope.
- 1.12 Brush control handles and biopsy port. Brush around valve seats.
- 1.13 Clean valve seats thoroughly - check that all visible debris has been removed.
- 1.14 Fit cleaning adaptors. Thoroughly flush all channels with fresh detergent (not used on any other instrument previously). Ensure all air from the channels has been displaced then leave solution in contact for product specified time.
- 1.15 Purge detergent solution from all channels.
- 1.16 Rinse outer surfaces. Flush all channels thoroughly with fresh water (this means tap water that has been freshly drawn and not used for any other instrument). It is essential that all detergent be removed prior to disinfection.

- 1.17 Purge channels with air to remove rinsing water.
- 1.18 Disinfect as per Section 2 below or reprocess in AFER. Note: some AFERs perform the flushing of the detergent and instruct that the endoscope be connected to the AFER after 1.13 as the product used for cleaning is integral to the outcome of the disinfection process. For AFERs that do not have individual channel flow alarms and that perform the flushing process, the patency of each channel should be ascertained prior to the endoscope being placed in the machine.
- 1.19 A recently released AFER is approved to be used as a complete reprocessing machine (see AFERs). The endoscope is processed up to removing the valves and buttons in step 1.5 and is then placed into the machine, which performs the leak testing, cleaning, disinfection, alcohol perfusion and drying. Time after use is critical and must not exceed 1 hour.

## 2. Manual disinfection

- 2.1 After manual cleaning immerse endoscope in disinfectant solution so that the entire endoscope is submerged. Fill all channels with disinfectant solution so that all air bubbles are expelled. All channel entrances must be under the surface of the disinfectant during this procedure to ensure that no air enters the channel. Remove the buttons and valves from the ultrasonic cleaner; rinse, dry and then immerse in disinfectant solution as per 2.2 or prepare for steam sterilisation. Extra supplies of buttons and valves will be needed if the time taken for ultrasound cleaning of buttons will delay further endoscope processing or if the ultrasound cleaning is performed in another location e.g. Central Sterilising Services Department (CSSD).
- 2.2 Soak instrument for required time at the required temperature in disinfectant solution of choice (see page 29). A timer with an alarm is essential to ensure that accurate soak times are achieved; digital timers avoid errors that occur when selection is by rotary dial. A fluid thermometer with digital readout is recommended to continuously monitor temperature of the disinfectant solution.

- 2.3 Purge disinfectant solution from all channels with air while endoscope is submerged then remove endoscope, valves and buttons from disinfectant solution, taking care to avoid drips and splashes as these will expose staff to hazardous chemicals.
- 2.4 Rinse exterior of endoscope thoroughly and flush channels with fresh water to remove traces of chemical (for rinse water quality, see page 28; for rinse volumes, see page 29). Rinse all valves and buttons thoroughly.
- 2.5 Purge all rinsing water from channels with air.
- 2.6 Dry instrument channels with pressurised air.
- 2.7 If the instrument is being prepared for reuse, remove the cleaning adaptors. Dry exterior surfaces with a soft cloth and reassemble endoscope.

*If the instrument is to be stored do not remove cleaning adaptors and refer to point 3.1.*

## 3. At the end of the list

- 3.1 Flush all channels with 70% alcohol (ethyl alcohol or isopropyl alcohol) using approximately 2 mls for the elevator or balloon channel and approximately 20 mls for each other channel.<sup>238</sup> If using a multi-channel cleaning adaptor the quantities of alcohol may need to be increased. Methylated spirits is not suitable for this process.
- 3.2 Force air dry all channels until no moisture emerges from the distal tip. Ensure that the air source has a flow regulator and use lower pressure on fine channels. Use bayonet (luer slip) fittings rather than luer lock to attach the air tubing to the cleaning adaptors and fit securely but not tightly - if safe pressure is exceeded the bayonet fitting will give way. Use of excessive air pressure may cause damage to the instrument.
- 3.3 Remove all channel adaptors.
- 3.4 Ensure that all outer surfaces are dry.
- 3.5 Check the instrument for any sheath or lens damage. Polish the lens with the cleaner provided by the manufacturer. **DO NOT REASSEMBLE ENDOSCOPE FOR STORAGE.**

## 4. Storage

It has been shown that inadequate storage can lead to persistence or even a build-up of micro-organisms in experimentally contaminated endoscopes<sup>239</sup>. Studies have shown that when an endoscope has been correctly disinfected and meticulously dried as per these guidelines, no growth of micro-organisms can be detected from the channels of endoscopes stored for up to and in some cases longer than 7 days<sup>240,241,242,243,244,245</sup>. These studies examined endoscopes stored in standard cupboards (both with and without doors) or commercially available purpose-built drying cupboards that stored endoscopes vertically or horizontally. The evidence from these studies has led to the following recommendations<sup>246</sup>.

- a) Cupboards used to store endoscopes must be either designed to
  - hold endoscopes horizontally on a flat surface with continuous air flow through each channel, **or**
  - be tall enough to allow endoscopes to hang vertically without touching the floor and be well ventilated or have continuous air flow through each channel.
- b) Cupboards with continuous air flow should provide filtered air, flow monitoring and audible alarms in the event of failure. If air flow fails, the connections to the cupboard air flow lines will impair fluid drainage and evaporation of residual moisture within the endoscope.
- c) Cupboards should be made of an impermeable material that allows for the cupboard walls to be cleaned weekly.
- d) Provided storage conditions are as recommended above, endoscopes will need to be disinfected prior to use only when the times in the following table have elapsed:

Type of endoscope	Storage time
Gastrosopes, colonoscopes, radial EUS scopes	72 hours
Duodenoscopes, bronchoscopes and linear EUS scopes	12 hours
Emergency endoscopes e.g. intubating bronchoscopes	72 hours
Enteroscopes	72 hours if stored with continuous flow air, 12 hours if hanging storage, as impractical to have hanging vertically without touching the floor

- e) Those endoscopes only used in emergency should be routinely reprocessed every 72 hours to ensure they are ready to be used at any time.
- f) Endoscopes must have a full disinfection process performed at the end of the list, using 70% alcohol and forced air drying to enhance the drying process prior to storage. Methylated spirits is NOT suitable for this process.
- g) Extended storage is only permitted if recent (within 12 months) routine microbiological surveillance of the endoscope has shown negative culture results.
- h) If recent culture results have been positive or if adequate storage facilities are not available, endoscopes should be disinfected prior to use if the storage time has been longer than 12 hours.
- i) Endoscopes should not be stored in transport cases as these may have become contaminated and do not allow air flow to remove residual moisture from the endoscope.

## 5. Reprocessing cleaning equipment

All reusable brushes used to clean the endoscope should be ultrasonically cleaned then steam sterilised after each use.

Cleaning adaptors and attachments including channel blockers and flushing systems must be reprocessed as per written manufacturer's instructions. Any cleaning adaptors/attachments that cannot be sterilised should be thermally disinfected in an appropriate machine (usually in a CSSD)<sup>235,247,248,249</sup>.

## 6. Endoscope accessory equipment

The cleaning and disinfection or sterilisation of reusable endoscopic accessories is equally as important as that of the endoscope because endoscopic accessories have been implicated in the transmission of infection and pseudo-outbreaks<sup>22,41,46</sup>.

**As with endoscopes, the cleaning of accessories as a prerequisite to sterilisation is mandatory.**

### a) Cleaning

1. All equipment should be immersed in detergent or other cleaning solution (page 27) immediately following use until cleaning can be performed.
2. The equipment should be dismantled as far as possible and all visible soiling removed.
3. Any spiral coil, hinged or complex-structured accessories should be placed in an ultrasonic cleaner and processed according to manufacturers' recommendations.  
**NB** Keep hands out and lid on.
4. Any fine-bore cannulae or tubing accessory items will require thorough flushing with detergent solution. Other accessory items, depending on design, will require a combination of flushing and brushing to clean surfaces.
5. Following cleaning by either of these methods, accessory items should be thoroughly rinsed and dried prior to disinfection, autoclaving or ethylene oxide sterilisation. **High-level disinfection should not be used for equipment that can be steam sterilised.**

### b) Disinfection and sterilisation

In general, accessory equipment used in gastroenterological procedures requires high-level disinfection. However, accessories that enter sterile tissue or the vascular system must be sterile. This includes biopsy forceps, injection sclerotherapy needles and all accessories used for ERCP. If an alternative exists, non-autoclavable reusable accessories should not be used.

1. All autoclavable equipment must be cleaned thoroughly prior to sterilisation.
2. All non-autoclavable equipment should first be thoroughly cleaned then immersed in disinfectant, ensuring all cavities are filled.

**Some accessory items require specific comment.**

**Water bottles and connectors.** These accessory items should be steam sterilised and a new bottle used for each session as they have been implicated in the transmission of infection<sup>250</sup>. All non-autoclavable bottles and connectors should be replaced with those that are fully autoclavable.

**Dilators** are likely to come in contact with tissue that has been abraded or otherwise damaged by the dilation process and this procedure is associated with a relatively high bacteraemia rate. Dilators should therefore be sterile or have undergone high-level disinfection. Dilatation is frequently performed using an endoscope that has undergone high-level disinfection.

## 7. Variation in cleaning and disinfection regimens depending upon the infective status of the patient

A number of surveys has shown that the practice of varying the cleaning and disinfection regimen according to the known infective status of the patient is widespread<sup>35,119,251,252,253,254</sup>. Reynolds et al reported that in up to half the endoscopy units surveyed in Massachusetts, staff changed their reprocessing techniques after procedures in patients with known HIV infection, tuberculosis or viral hepatitis<sup>35</sup>. Common practices included using ethylene oxide "sterilisation" or prolonging chemical immersion times for endoscopes used in patients with these diagnoses. Such an approach is illogical and potentially dangerous. Many patients who have these infectious diseases either do not know or choose to conceal such knowledge at the time of an endoscopic procedure. It is therefore imperative to have a cleaning and disinfection schedule that deals effectively with unrecognised and recognised cases, a principle that underlies all recommendations in this guideline.

The only exceptional situation is that of suspected pulmonary tuberculosis, which does not require any change in the cleaning and disinfection regimen but which should deter the bronchoscopist from undertaking a procedure in the first place due to the risk of airborne transmission to staff and other patients.

## 8. Reuse of medical devices labelled 'Single Use Only'

Major physical issues in reprocessing 'Single Use Devices' are clearly stated in the compliance policy guide of the FDA<sup>255</sup>. Reprocessors of Single Use Devices should be able to demonstrate:

1. that the device can be adequately cleaned and disinfected or sterilised.
2. that the physical characteristics or quality of the device will not be adversely affected by these processes; and
3. that the device continues to comply with applicable FDA requirements; i.e. will remain safe and effective for its intended use.

The commercial reprocessing of single-use devices as occurs in the USA has not become established in Australia or New Zealand. With the availability of autoclavable reusable items and relatively low-cost single-use items, it is unlikely that hospitals will choose to reprocess single-use devices. Institutions that do will face the necessity of developing and validating protocols that can ensure the safety and efficacy of reprocessed items, as detailed in the Australian Therapeutic Goods Administration regulations introduced in 2003<sup>256</sup>.

## Automated Flexible Endoscope Reprocessors (AFERs)

Machines designed to disinfect and rinse endoscopes are widely used in the western world<sup>257</sup>. It is now policy across much of Europe to no longer use manual disinfection and as a result, most units in that region now practice machine reprocessing<sup>254</sup>. The publication of ISO 15883 by the European Committee for Standardisation and the International Standards Organisation, in particular Parts 1 and 4 of these documents, provides an international machine standard that specifies requirements for manufacturers as well as guidance on routine and periodic tests for users to perform<sup>258,259</sup>. Modern AFERs, when correctly designed, installed, maintained and used, provide reliable and effective high-level disinfection, reducing unpopular, time-consuming, arduous and repetitive manual tasks and occupational exposure to irritant chemicals.

Most of the currently available AFERs do not negate the need for thorough manual cleaning as an essential prerequisite to mechanised disinfection.

However, the mechanisation of the cleaning step of reprocessing offers clear advantages in respect of reproducibility and standardisation. At the time of publication, one manufacturer now has a model of AFER that has been approved by the Therapeutic Goods Administration (TGA) to be marketed for use with the machine cleaning cycle replacing the manual cleaning step. Company data of efficacy are supported by one independent study recently published in a peer-reviewed journal<sup>187</sup>. One machine manufacturer and their expert advisors emphasise that time after use to reprocessing is critical and must not exceed 1 hour. Initial results of microbiological surveillance cultures from endoscopes fully reprocessed in this machine in routine clinical use in Australia show no evidence of contamination.

A study on another machine also shows a cycle with equivalent effectiveness to manual cleaning<sup>260</sup>. It is important to note however, that despite some machines having a cleaning cycle, unless the TGA approval to market has been based on the instrument not undergoing prior manual cleaning this step must be completed. Given the many reports of infection and pseudo-infection that have been caused by failure of staff to follow endoscope cleaning protocols and that surveys continue to demonstrate variability in manual cleaning practices, the increased use of cleaner-disinfector AFERs should lead to more reliable endoscope reprocessing in the future<sup>261,262,263</sup>.

A survey of practices in the United States in the early 1990's showed widespread lack of knowledge of the potential problems with machine contamination<sup>253</sup>. Although there is now a wider recognition of the problems associated with AFERs, there remains widespread ignorance of the importance of machine colonisation, the proper methods of decontaminating machines and the need for bacteriological surveillance. AFERs have been responsible for epidemics of pseudo-infection and many serious clinical infections, including patient deaths<sup>264,265,266</sup>. There is a wide variety of AFERs available, with variable efficacy and safety features<sup>267</sup>. Of particular risk is that of making the wrong choice of cycle (choosing a cycle of disinfection only vs detergent flush plus disinfection when cleaning of the endoscope has not been done manually). It is important that both AFER manufacturers and users are aware of the potential for and mechanisms of failures and work towards improved safety features and surveillance for problems.



## Machine design and principles

AFERs rarely show microbial contamination before six months after start of use but contamination becomes increasingly likely as the machine ages. Common predisposing causes include the development of biofilms, valve wear, surface irregularity, line fissuring and filter failures.

The following are ideal design features and principles that should underlie the selection and use of AFERs:

### 1. Water supply

AFERs should be plumbed into the water supply rather than use manual filling. It is necessary to install filters in the water supply before its entry into the machine and membrane filtration of 0.2 micron is necessary for final rinsing. Once filter systems are installed they in turn must be regularly serviced and monitored. It is all too easy for filters themselves to become a source of contamination.<sup>23,224,227</sup> For further discussion see section on Water – see page 28.

### 2. Water reuse

Fresh water should be used for each cycle to avoid disinfectant and microbial contamination of rinse water.

### 3. Fume containment

Provision should be made for the extraction of disinfectant fumes from within the machine or the machine should be contained within a fume extraction hood.

### 4. Disinfectant supply

AFERs that use a concentrated solution and in-use dilution for a single cycle (e.g. STERIS System, Reliance, Soluscope, Medivator Advantage, Evotech) avoid the problem of dilution of the disinfectant with rinsing water. Machines that contain a tank of disinfectant for re-use should be monitored for disinfectant concentration to determine appropriate disinfectant change schedules. Machines that require filling of a disinfectant reservoir must incorporate a pump mechanism to obviate the need for pouring of solutions into the machine, which would potentially expose staff to the disinfectant and vapours.

### 5. Cycle counter

Visual display and a permanent record of the cycle number should be available to indicate the appropriate time for disinfectant change. Automatic recording of disinfection activity is desirable.

### 6. Auto-disinfection

All machines should have a cycle for auto-disinfection, during which internal piping and reservoirs are disinfected. Unfortunately in a few older machines the auto-disinfection cycle does not include all necessary parts of the machine, which may allow significant contamination to develop.

Heat is the preferred method for auto-disinfection. Alternatively, the auto-disinfection cycle should use a different disinfectant to that routinely used in the reprocessing cycle. A number of micro-organisms, including atypical mycobacteria (particularly *Mycobacterium chelonae*), can become resistant to glutaraldehyde<sup>198</sup>, and elimination of these colonising micro-organisms may require purging of the whole system with chlorine-releasing disinfectants, peroxide compounds or absolute alcohol. The problem is not limited to mycobacteria and glutaraldehyde: bacteria isolated from an AFER using chlorine dioxide as a high-level disinfectant can be demonstrated to be relatively resistant to this and similar disinfectants and resistant strains of *Pseudomonas aeruginosa* have also been identified<sup>268</sup>.

### 7. Drying

A drying cycle using filtered air should be complemented by a facility that irrigates the channels of the endoscope with alcohol.

### 8. Leak testing

AFERs should perform leak testing of the endoscope at least once during the reprocessing cycle with automatic detection alert or cycle-abort indication if testing fails.

### 9. Warning systems

Measurement of all channel flow rates and pressures should be monitored and an audible warning alert should sound when there are significant changes in these parameters. This is essential to detect channel blockage preventing adequate perfusion of disinfectant solutions, dislodged connectors, water filter blockage, leakage from split channels and other faults.

### 10. Proof of process

A printout of cycle parameters should be incorporated. This information should also be electronically transferable to computer-based record systems.

### 11. Heating facility

A heating facility allows for lower in-use concentration of disinfectant and shorter contact time. The temperature should be monitored if heated disinfectant is used in the machine, and the disinfectant chosen be licensed by the TGA for use at the elevated temperature.

### 12. Individual channel perfusion

The AFER must have enough connections to allow perfusion of all channels of the endoscope. Fluid flow through each channel should be ensured by a design that does not permit diversion of flow to a channel of lower resistance. For example, AFERs that are to be used for reprocessing duodenoscopes must allow for the differential pressures required to perfuse the

widely differing sized channels, including the fine-bore forceps elevator channel; similar issues arise with perfusion of jet washing and balloon channels.

### 13. Maintenance

A maintenance schedule that ensures tanks, pipes, strainers and filters of both the machine and water treatment system are kept free of biofilms and other deposits should be instituted.

### 14. Microbial monitoring

Microbial monitoring of AFERs and endoscopes is essential. Machines shown to be contaminated should not be used until cleaned and proven to be microbiologically safe (see Microbiological surveillance cultures - page 39). Machines returned from repair or received on loan should undergo testing prior to use.

## Endoscopes for repair and on loan

### Damaged endoscopes being sent for repair:

1. Unless there is a suspected leak, fully clean, disinfect and dry all endoscopes before sending them to a manufacturer for repair. If there is a suspected leak, contact the manufacturer for instructions on reprocessing and transport.
2. Advise the company of the most recent reprocessing that has been undertaken on that endoscope and send documentation or confirmation of this with the endoscope.
3. In most circumstances, the endoscope does not need to be placed in a biohazard bag; in exceptional circumstances (such as an uncleaned endoscope or under infection control advice) place the endoscope in a biohazard bag or sheet and notify the courier of the biohazard status.
4. Send endoscopes in the appropriate endoscope carrying case.

### Endoscopes being received on loan or on return from repair:

1. The internal channel configuration diagram should be provided with all endoscopes received on loan.
2. A copy of the most recent microbiological test results should be requested from the supplier of loan instruments.
3. All endoscopes returning from servicing or received on loan are to be manually cleaned and disinfected prior to use.

4. Endoscopes can be used following cleaning and disinfection and do not need to be kept quarantined while awaiting microbiological surveillance test results.
5. A microbiological surveillance culture for bacteria should be performed within 72 hours of receipt of the endoscope.
6. If the culture is positive, follow instructions in the Quality Control section below.

## Quality control

Quality control is fundamental to the delivery of safe and effective clinical services. This is especially important in endoscopy because the equipment is so difficult to clean and disinfect, and because failure of reprocessing has led to hundreds of reported infections following endoscopy procedures. These failures have commonly been attributed to non-adherence to up-to-date guidelines and have involved a variety of human errors and equipment faults. Failures in endoscope reprocessing are relatively common – a task force in England investigated 21 incidents in 2003 and 2004<sup>269</sup>. These facts support the need for a comprehensive and multi-factorial quality control program in every endoscopy unit.

## Proof of process

### Accreditation, approval and training

1. Endoscopy should only be undertaken at sites that have adequate facilities for cleaning and disinfection<sup>270</sup>. An audit tool for sites has been developed to allow staff to identify if their practice is in compliance with these GESA/ GENCA guidelines and may be accessed at ([http://www.health.qld.gov.au/EndoscopeReprocessing/document/audit\\_endoscopy.doc](http://www.health.qld.gov.au/EndoscopeReprocessing/document/audit_endoscopy.doc))<sup>271</sup>.
2. Only staff who have completed a structured education program and who have had their competency to perform the vital tasks of cleaning, disinfection and sterilisation assessed, or those undergoing supervised training, shall carry out these tasks<sup>272</sup>.
3. These staff should have a clear understanding of both the important principles involved in cleaning and disinfecting endoscopes and accessories (see previous sections) and the details of each step necessary in reprocessing.
4. The laboratory that performs microbiological testing must be NATA accredited and may have ISO 17025 or ISO 9007 certification.

## Documentation required

These records prospectively ensure that staff are following the correct procedure, and the equipment and solutions are functioning correctly at the time of reprocessing each endoscope. These records also allow retrospective investigation into the possible transmission of infection or the source of endoscope contamination. Records to be kept include but are not limited to the following:

### 1. Every list

- Order of patients on the list.

### 2. Every endoscope reprocessed

- Date of procedure.
- Patient details – this could be formatted on a facility label. The name is to be recorded against the details of the process that prepared the instrument ready for use on that patient.
- Instrument details (individual serial number).
- Name of the person who completed the manual cleaning phase of reprocessing and either immersed the endoscope in disinfectant or who connected the endoscope to the AFER machine.
- Name of the person who removed the instrument from the disinfectant solution and completed the post-disinfection phase or who removed the instrument from the AFER and released the endoscope as ready for patient use.
- For manual disinfection systems:
  - Temperature of the disinfectant.
  - Immersion time in the disinfectant.

### 3. Daily or as per product instruction

- Minimum effective concentration (MEC) of reusable disinfectant.
- Name of the person who tested the reusable disinfectant.

### 4. Other

- Batch number of disinfectant.
- Date reusable disinfectant decanted into tank.
- Date reusable disinfectant changed or topped up (to maintain volume).
- Ultrasonic testing.
- Water filtration pressure check.

A unit-based record shall be kept regardless of whether the information is in the patient's health care record. Computer print-outs from an AFER shall be attached to the unit record and a copy may be attached to the patient's health care record.

Each endoscopy unit should develop its own documentation system that meets its own particular needs. A sample template is included in Appendix A and various templates may be accessed on the Endoscope Reprocessing website ([http://www.health.qld.gov.au/EndoscopeReprocessing/module\\_6/6\\_3.asp](http://www.health.qld.gov.au/EndoscopeReprocessing/module_6/6_3.asp)). They have been developed by particular units for their own use and are included as examples only.

## Monitoring the disinfectant

Concentration of a disinfectant is critical. In general the lower the concentration of the agent, the longer it will take to kill the same number of micro-organisms. To achieve the minimum high-level disinfection required for reprocessing endoscopes the concentration and temperature of the disinfectant and the contact time with the instrument must be in accordance with the disinfectant's TGA registration. This is reflected in the manufacturer's instructions on the disinfectant's label.

The most critical factor in the use of any disinfectant is thorough meticulous manual cleaning. If the flexible endoscope or its accessories are not clean then high-level disinfection or sterilisation cannot be achieved.

The challenges of micro-organisms and organic matter, dilution by rinse water and age of the chemical solution result in a gradual reduction of the effectiveness of reusable disinfectants. The appropriate number of reuses must be determined by testing that the solution is at or above its minimum effective concentration (MEC).

- The MEC of the reusable disinfectant solutions must be checked daily or more frequently depending on the numbers of instruments being reprocessed. For OPA use, the MEC must be checked for each use of the disinfectant.
- Use a test strip or other approved device specific for the type and brand of disinfectant
- Record the results of the concentration testing and the name of the person performing the test
- The disinfectant must be changed when the solution falls below the MEC **OR** if it exceeds the manufacturer's recommended use life, **WHICHEVER COMES FIRST**. Do not extend the in-use life of the disinfectant solution beyond the manufacturer's recommendations, even if the concentration remains above the MEC.



## Validation of ultrasound cleaning

An ultrasonic cleaner enables thorough cleaning of accessory equipment by ultrasonic agitation that dislodges soil from the instruments. Protocols for reprocessing these devices have been validated with ultrasound cleaning as an integral step.

To ensure correct functioning, empty the tank, clean the ultrasound machine and replace the cleaning solution at least daily or more frequently if the solution becomes visibly soiled. Solution will need to be degassed prior to use.

The efficacy of the ultrasonic cleaner should be tested each day the cleaner is used. Testing should be performed according to the manufacturer's instructions and in keeping with AS2773.2 section 6. Results of the testing shall be documented as part of the proof of process. According to AS 2773 either of the following two tests can be used to check the performance of the ultrasonic cleaner.

### 1. Pencil load test

This is also known as the ceramic disc test. The surface of an unglazed ceramic disc or plate having a matt finish and a diameter of approximately 50mm (thickness is not critical) is rubbed with a standard HB lead pencil and then immersed in the cleaning tank. A ground-glass stopper, a sheet of ground glass or an aluminium sheet with a thickness of 2 – 3mm may be substituted for the ceramic disc. A kit using an aluminium disc is commercially available. The ultrasonic cleaner should completely remove the pencil lead within 3 minutes or the time specified on the kit instructions.

### 2. Aluminium foil test

Vertically suspend pieces of aluminium foil in the ultrasonic tank, so that they are evenly spaced between the ends of the cleaning tank. Each piece of foil should be approximately 0.025mm thick and extend to approximately 6mm clear from the sides and bottom of the tank. It may be necessary to provide a simple wire frame to support each sheet of foil during the test.

Operate the ultrasonic cleaner for 10 seconds. Remove the sheets of foil and observe the number and distribution of perforations and wrinkles. Ideally, all sheets of foil should be similarly perforated and wrinkled. That is, if the holes are primarily in the middle sheet of foil, or if the pieces of foil are only wrinkled but without holes, the equipment is considered to have failed the test. On completion of the test, ensure that the tank is drained and thoroughly cleaned, to remove the foil residue.

## Accessories

All accessory items that have been sterilised, e.g. biopsy forceps, must have a chemical indicator to demonstrate that they have been subjected to the sterilisation process.

## Microbiological surveillance cultures

### Introduction

Microbiological surveillance of endoscopes and AFERs has proven to be one of the most difficult and controversial areas of infection control in endoscopy. Surveillance cultures of endoscopes and AFERs as a quality control measure has been recommended by the Gastroenterological Society of Australia and the Gastroenterological Nurses College of Australia since 1995<sup>273</sup>, and endoscope surveillance cultures were also recommended by the New Zealand Standards Expert Committee in 2002<sup>274</sup>. As a result, the majority of endoscopy units in Australia and New Zealand have routinely been performing these cultures. Endoscope surveillance cultures are also recommended by the French Gastroenterology Society<sup>275</sup>, Canadian endoscopy working group<sup>276</sup>, the German Working Group on Hospital Hygiene<sup>277</sup>, the Robert Koch Institute, the Asian Pacific Society of Digestive Endoscopy and the European Society of Gastroenterology (ESGE), and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA) have published formal guidelines for this practice<sup>278,279,280</sup>. In addition, the requirement in European Standard EN ISO 15883 for the clinical service provider to evaluate outcome quality by technical and microbiological testing of washer disinfectors, endoscopes and water has led ESGE/ESGENA to also publish guidelines for process validation and routine testing<sup>259</sup>. However, the adoption of microbiological surveillance of endoscopes and AFERs is not universal; the American College of Chest Physicians and American Association for Bronchology and a panel representing a number of United States Gastroenterology and Infection Control groups make no recommendation for routine surveillance cultures of endoscopes and only 17% of Northeastern USA endoscopy units perform endoscope surveillance cultures<sup>281,282,283</sup>.

## Rationale

Poor compliance with guidelines for endoscope reprocessing, occult endoscope damage and faulty or contaminated automated flexible endoscope reprocessors will continue to threaten the safety of patients undergoing endoscopy. Endoscope and AFER cultures have identified breakdowns in infection control before they were otherwise detected or that would not have been detected by other quality control measures<sup>12,284,285,286,287</sup>.

Over a three-year period in which more than 7000 endoscope surveillance cultures were performed in 37 New Zealand endoscopy units, one episode of inadequate cleaning and nine episodes of faulty endoscopes (mostly damaged channels) were identified by positive cultures (unpublished data). Some authors reporting recent endoscopy-related outbreaks or pseudo-outbreaks have stated or implied that surveillance cultures could have detected the faults and an increasing number of authors are promoting endoscope surveillance cultures<sup>12,18,19,285,286,288,289,290</sup>. Experience in Australia and New Zealand has shown that the published recommendations for interpretation of positive findings have allowed users to deal appropriately with insignificant contaminants, and that negative cultures at a time of minor infection control breakdowns have helped to avoid unnecessary patient recall and testing. The published positivity rate of routine endoscope surveillance cultures has varied from high to very low<sup>189,291,292,293</sup>. The recommendations for surveillance cultures below represent the minimum expected of an Australasian endoscopy unit.

## Recommendation

We promote the use of endoscope and AFER surveillance cultures as a quality control marker of the adequacy and completeness of the entire cleaning and disinfection process and the structural integrity of the endoscope. The recommendations for when and how to perform these cultures are based on the international literature and local anecdotal experiences.

## Testing – What to look for

### 1. Bacteria

Bacterial cultures should be directed to the detection of:

a) In gastrointestinal endoscopes:

Oral and enteric micro-organisms such as coliforms (including *Salmonella*), enterococci and viridans streptococci (but not anaerobes) and non-fermentative gram-negative bacilli (including *Pseudomonas* spp.).

b) In bronchoscopes:

As for gastrointestinal endoscopes **plus** rapid-growing mycobacteria. Culture to identify *Mycobacterium tuberculosis* is not included in routine surveillance but is performed when there is a suspected outbreak or pseudo-outbreak of *M. tuberculosis* infection in patients who have undergone bronchoscopy.

c) In automated processors:

Non-fermentative gram-negative bacilli (including *Pseudomonas* spp.) and rapid-growing mycobacteria.

We do not recommend routine testing for *Legionella* spp., anaerobes or *Helicobacter pylori*.

### 2. Viruses

Routine microbiological surveillance for viruses is not recommended because:

- a) The detection of intact infective viruses is too complex and expensive for routine surveillance purposes. Many viruses, e.g. HBV, cannot be cultured in vitro<sup>89</sup>. The detection of viral nucleic acid by PCR techniques (see Hepatitis C page 13) certainly does not necessarily reflect the presence of intact infective viral particles.
- b) Deva et al have shown that bacterial contamination after reprocessing is an accurate reflection of viral contamination<sup>190</sup>. Where bacteria remained on or in an endoscope after reprocessing, often there was also remaining viral material. Conversely, in no case where all bacterial contamination had been removed were remaining intact viruses demonstrated.
- b) Viruses can only proliferate within cells. Therefore proliferation in the internal channels of endoscopes or in automated reprocessors does not occur.

## Frequency of testing

Because of differential risks of infection transmission, recommendations which are themselves empiric, vary with both the proposed use of endoscopes and with the method of disinfection:

- 1. AFERs should be monitored every 4 weeks.
- 2. Duodenoscopes, bronchoscopes and linear endoscopic ultrasound instruments should be monitored every 4 weeks.
- 3. All other gastrointestinal radial ultrasound endoscopes should be monitored every 3 months.

4. Endoscopes that have been reprocessed through a sterilisation cycle and stored in a wrapped state should be monitored every 3 months.
5. The water used for manual rinsing of endoscopes should be monitored every 4 weeks if a filter bank is not in use or every 3 months where rinse water is filtered to 0.2 microns<sup>294</sup>.
6. Endoscopes on loan are to be tested within 72 hours of receipt of the instrument. The loan instrument should then be retested according to the routine schedule for the type of endoscope if it remains on loan for that period of time.
7. Further microbiological screening may be undertaken in consultation with a Clinical Microbiologist if:
  - There is a clinical suspicion of cross-infection related to endoscopy;
  - Positive surveillance cultures occur;
  - Alterations are made to the plumbing of the endoscopy reprocessing area;
  - New reprocessing protocols are introduced in the unit;
  - New models of equipment (endoscope or AFER) are used;
  - As a means of quality check for new staff responsible for endoscope reprocessing.

### Microbiological testing protocols

Instruments should be sampled after usual processing and following storage of at least 12 hours to allow detection of micro-organisms arising from a biofilm. Endoscopes that have undergone sterilisation and been stored in a wrapped state should be removed from the packaging and tested at the interval indicated above.

### Method of sampling – endoscopes

1. 10 ml of sterile water or normal saline is withdrawn from a freshly opened container using a sterile cannula/needle and syringe and put into a sterile specimen container.
2. 10 ml of sterile water is flushed into each of the channels to be brush sampled. Any fluid that emerges from the distal tip is collected into the sterile specimen container. Attention should be paid to keeping the tip of the endoscope from touching the container so as to avoid contamination.
3. A sterilised or single-use endoscope brush is passed down the biopsy channel, withdrawn and swirled in the container containing the sterile water. This procedure should also be performed on air and water channels of CO<sub>2</sub>, balloon endoscopes designed with brushable

channels. The brush will need to be handled using sterile gloves; sterile gowns are optional. Reusable endoscope brushes should be cleaned and sterilised by steam under pressure or low temperature sterilisation prior to sampling.

4. Using a sterile syringe, aliquots of sterile water are flushed through each of the air and water channels, suction channel and the forceps elevator, and jet channels where applicable. Flushing should be performed from the connection points in the light guide plug and flow to the distal tip. The volume of fluid required is different for each endoscope and will vary from 5 to 50 ml. Fluid should be flushed until it emerges from the distal tip. Air is then syringed through to empty the remaining fluid from each of the channels. The total rinse fluid is collected in a sterile specimen container.
5. The samples should be pooled in a single container that is labelled and sent with a request form detailing the following:
  - a) Type of endoscope sampled and serial number.
  - b) Name of person to whom report should be sent.
  - c) Test requested (see “What to Look For” page 40).
6. In the event of a persistently positive surveillance culture from an endoscope, the individual channels may need to be sampled and the rinse fluid placed into separate collection containers.
7. Antegrade sampling may need to be supported by retrograde sampling in selected instances; e.g. suspicion of clinical transmission, irregular positive cultures, AFER contamination, “pseudo-infections” associated with bronchoscopy. Retrograde sampling is obtained by using the suction button of the endoscope to suction back the fluid used for flushing, to the proximal channel opening<sup>12</sup>.

### Method of sampling – AFERs

Early detection of machine contamination is best effected by a concentration process. The exact method of sample collection for AFERs will vary depending upon the design of the individual machine.

Connect a sterile sealed bacteria-retentive 0.2 microns or 0.45 microns filter to the outlet of the machine where it normally attaches to the endoscope and cycle at least 200 ml of fluid through the filter in the rinse cycle mode. When completed, the filter should be placed into a specimen container and forwarded to the laboratory. There the disc can then be removed and plated directly.

### Method of sampling water for manual rinsing or the water supply to an AFER.

It is likely that a concentration process will also best effect detection of rinse-water micro-organisms. Following wiping of the tip of the water faucet with 70% alcohol and allowing it to air dry, run 50 ml through the faucet and discard. Then using aseptic handling techniques, collect a 400 ml sample of water in a sterile container and send to the laboratory where a filtration process will concentrate the sample<sup>24</sup>.

**Note:** Micro-organisms (especially *Pseudomonas spp.*) can multiply in fluids. Any delay, such as samples being collected in the late afternoon and not processed until the following day, may lead to erroneous results. Therefore it is essential that the sample is promptly processed after collection. If there is likely to be any delay the sample should be refrigerated.

### Laboratory procedure

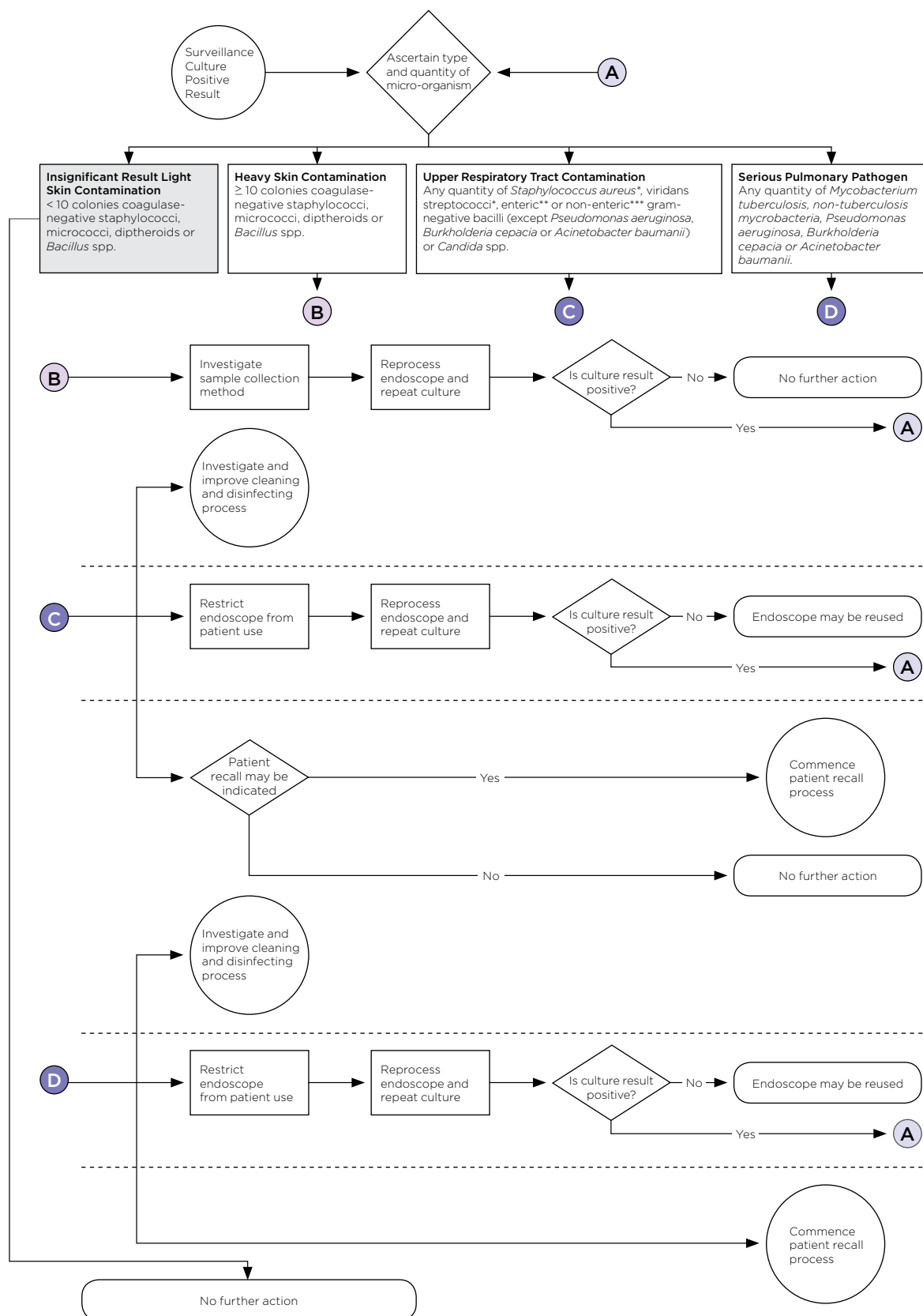
1. Centrifuge the collected sample for 15 minutes at approximately 3000 rpm, then decant to 1 ml and resuspend.
2. Inoculate 0.1 ml sample onto each of two blood agar plates.
3. Incubate one plate at 35°C and the other at 28°C for 7 days under aerobic conditions. Plates will need to be checked at 48 hours to identify rapidly growing bacteria and attention paid to ensure the plates do not dry out.
4. Perform semi-quantification of bacterial growth, e.g. no growth, 1 to 10 colonies, 10 to 100 colonies, > 100 colonies.
5. Identify any micro-organisms isolated as far as necessary to allow interpretation as detailed below and in the following flow charts. Sensitivities are not routinely required.
6. If there is any growth of micro-organisms the unit that sent the samples should be notified that working day.
7. Place microfilter discs used to sample the final rinse water of an automated reprocessor directly onto a blood agar plate and incubate aerobically for 2 days at 35°C then at 28°C for 3 days.

### Interpretation of cultures

Each endoscopy unit in conjunction with a Clinical Microbiologist must set its own threshold for the initiation of action if cultures are positive. The flow charts reprinted from the New Zealand Standards will guide decision making<sup>274</sup>. In addition, some examples are given opposite:

1. Low numbers of skin micro-organisms, such as *Staphylococcus epidermidis*, are most likely to represent collection process contamination rather than a significant problem with the disinfection or cleaning process. The most appropriate initial response is to review the sample processing technique to reduce the chance of contamination e.g. use sterile long-sleeved gown and sterile brush.
2. A growth of *Pseudomonas spp.* or other non-fermentative gram-negative bacilli from a duodenoscope, bronchoscope or an AFER that processes duodenoscopes or bronchoscopes would be cause for serious and immediate concern. This is a high-risk clinical situation and the immediate responses should include removing the AFER and endoscope from service, careful culturing of the AFER to see if it is the source of contamination, careful inspection of the endoscope for defects and repeated cultures after manual reprocessing to see if contamination persists. Clinical follow up of patients recently undergoing ERCP or bronchoscopy procedures with that endoscope would also be indicated.
3. Significant numbers of enteric micro-organisms, such as *E. coli* or enterococci being repeatedly recovered from one instrument only suggests that there is a mechanical defect in that instrument and it requires careful inspection with replacement of the channels if no other defect can be identified.
4. Significant numbers of enteric micro-organisms, such as *E. coli* or enterococci, being recovered from a variety of instruments within the unit suggests inadequate reprocessing, most likely defects in the manual cleaning program. Much less likely would be a problem in an AFER, (e.g. worn valves, serious biofilm accumulation). The appropriate response here would be a detailed review of **all** staff members' cleaning and disinfection techniques, if necessary by an independent assessor.
5. Culture of *Mycobacterium tuberculosis* from a flexible bronchoscope is a serious problem. Responses would include removal of the bronchoscope from service, mechanical review of the instrument by the manufacturer, review of any AFER used (including detailed cultures), and clinical surveillance of patients recently bronchoscoped with that instrument.
6. Growth of *Mycobacterium chelonae* from a bronchoscope is almost certainly due to a contaminated AFER that needs to be taken out of service and decontaminated.
7. **ANY** isolation of *Salmonella* or *Shigella* should cause concern.

## Response to positive bronchoscope cultures



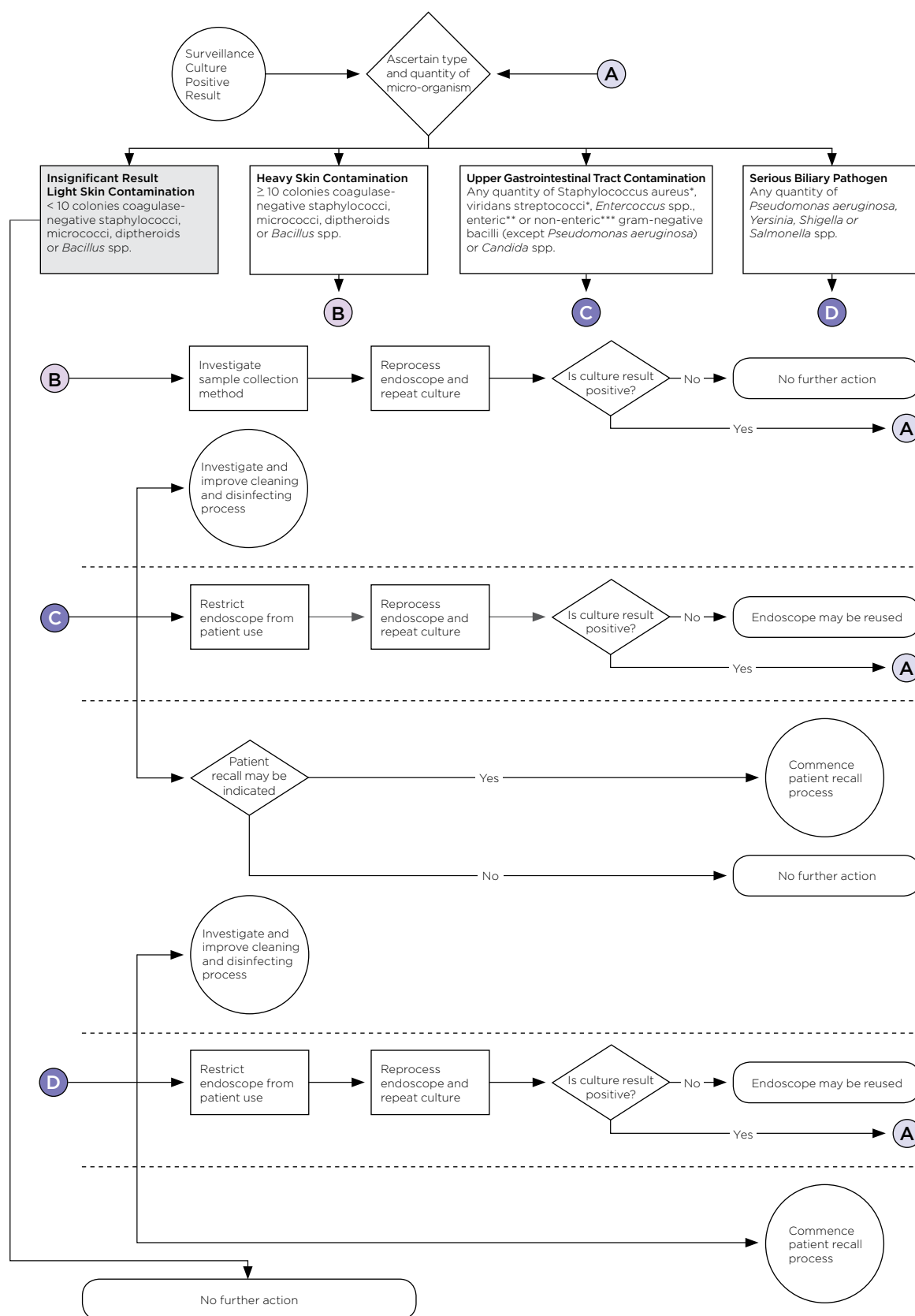
--- The horizontal dashed lines in each process separate pathways that must **each** be followed.

\* *Staphylococcus aureus* or viridans streptococci, when found together with coagulase-negative staphylococci, micrococci, diptheroids or *Bacillus* spp., should be treated as skin contaminants.

\*\* Enteric gram-negative bacilli include: *Escherichia coli*, *Klebsiella* spp., *Enterobacter* spp., *Serratia* spp., *Morganella* spp., *Citrobacter* spp. and *Proteus* spp.

\*\*\* Non-enteric gram-negative bacilli include: *Pseudomonas* spp. (including *Pseudomonas aeruginosa*), *Alkaligenes* spp., *Flavobacterium* spp., *Stenotrophomonas maltophilia* and *Acinetobacter* spp.

## Response to positive duodenoscope cultures



--- The horizontal dashed lines in each process separate pathways that must **each** be followed.

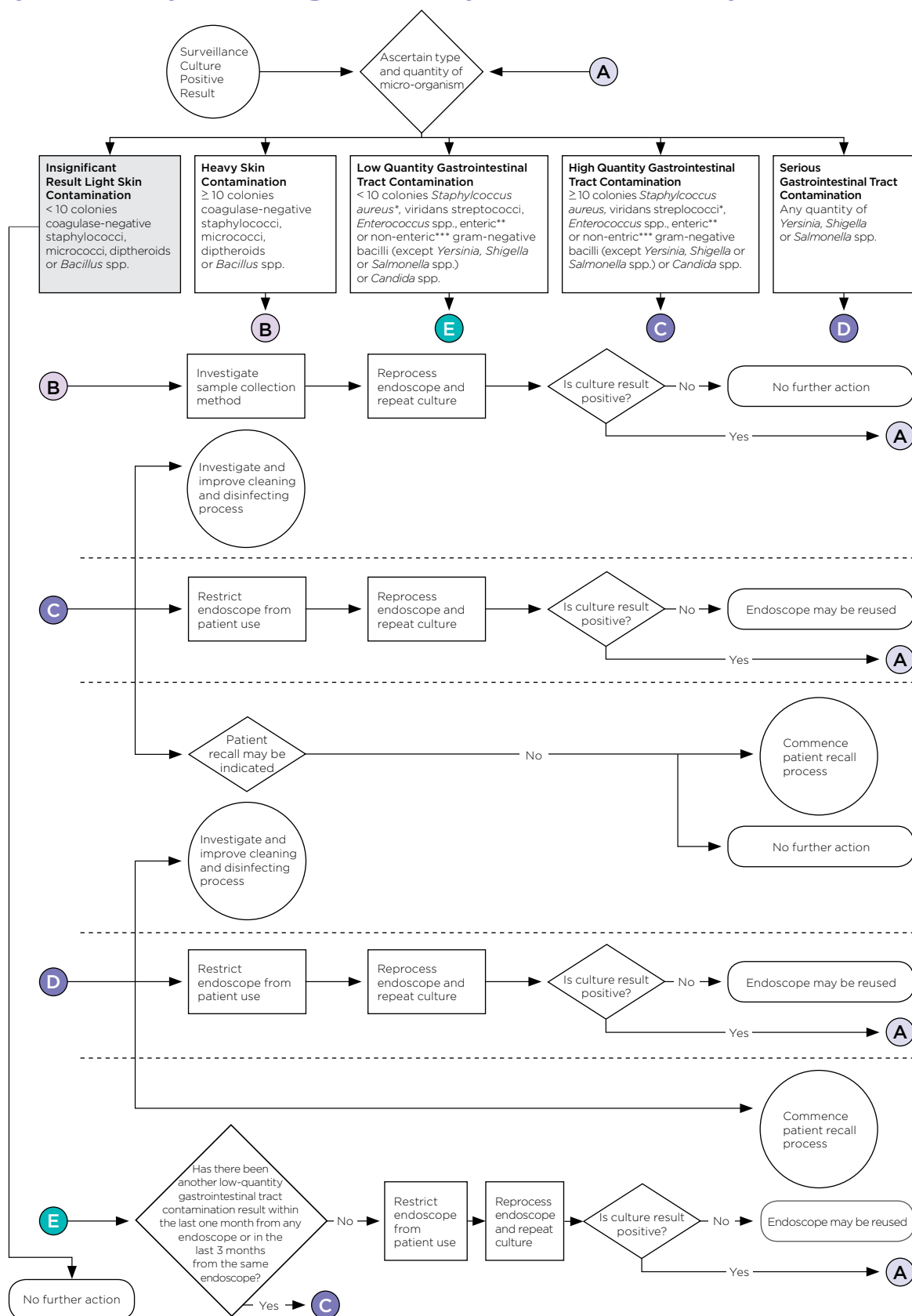
\* *Staphylococcus aureus* or viridans streptococci, when found together with coagulase-negative staphylococci, micrococci, diptheroids or *Bacillus* spp., should be treated as skin contaminants.

\*\* Enteric gram-negative bacilli include: *Escherichia coli*, *Klebsiella* spp., *Enterobacter* spp., *Serratia* spp., *Morganella* spp., *Citrobacter* spp. and *Proteus* spp.

\*\*\* Non-enteric gram-negative bacilli include: *Pseudomonas* spp. (including *Pseudomonas aeruginosa*), *Alkaligenes* spp., *Flavobacterium* spp., *Stenotrophomonas maltophilia* and *Acinetobacter* spp.



## Response to positive gastroscop or colonoscope cultures



--- The horizontal dashed lines in each process separate pathways that must **each** be followed.

\* *Staphylococcus aureus* or viridans streptococci, when found together with coagulase-negative staphylococci, micrococci, diptheroids or *Bacillus* spp., should be treated as skin contaminants.

\*\* Enteric gram-negative bacilli include: *Escherichia coli*, *Klebsiella* spp., *Enterobacter* spp., *Serratia* spp., *Morganella* spp., *Citrobacter* spp. and *Proteus* spp.

\*\*\* Non-enteric gram-negative bacilli include: *Pseudomonas* spp. (including *Pseudomonas aeruginosa*), *Alkaligenes* spp., *Flavobacterium* spp., *Stenotrophomonas maltophilia* and *Acinetobacter* spp.

## Investigation of possible infection transmission by endoscopy

The approach to such an investigation depends on the source of the initial concern. For example, a complaint may be received from a patient who became ill or was found to be infected with a blood-borne virus after endoscopy. Clinical staff may notice patients with a similar disease after endoscopy or the laboratory staff may isolate the same micro-organism from a cluster of patients who have recently had endoscopy. Other investigations are triggered by identification of a fault in an item of equipment or product (e.g. batch of disinfectant) or by a breakdown in protocol (e.g. a new staff member has not been using the correct channel connectors). Finally, positive surveillance endoscope or AFER cultures may be the first indication of a transmission event<sup>295,296</sup>.

1. Don't ignore or trivialise evidence of a problem.
2. Ask for independent help early and be open, honest and co-operative. Initial advice could be sought from an Infection Control Practitioner, Epidemiologist, Public Health Specialist or Infectious Diseases Specialist. Members of the GESA/GENCA guidelines writing committee are experienced with investigating possible transmission events and are willing to be contacted for advice.
3. Inform key stakeholders if a significant problem is confirmed (medical and nursing directors, risk management staff).
4. Immediate action and investigations depend on the presenting scenario (see table opposite).
5. If transmission of infection or a major problem with endoscope cleaning or disinfection is suspected, wider investigation and public notification may be indicated. Before undertaking this, establish an appropriate local, state or federal working group to manage the process. Consider the following members of the working group:
  - a) Endoscopy Unit Manager
  - b) Relevant clinicians
  - c) Infection Control Practitioner, Epidemiologist or Public Health Specialist
  - d) Microbiologist and/or Infectious Diseases Specialist

- e) Relevant administration staff from the organisation
- f) State or federal health representatives (essential – likely to take overall responsibility for the investigation)
- g) The manufacturers of any equipment or product implicated in the problem
- h) Someone with expertise in communication
- i) A lawyer  
A representative of the local patient advocacy service.

The decision to recall and test patients at risk is difficult.

Benefits of patient recall and testing include:

- a) Detecting patients with infection or colonisation, which may make it possible to treat that infection and/or prevent transmission to others;
- b) Community and patient assurance that the clinicians and organisation are responsive and open.

Disadvantages of patient recall and testing include:

- a) Publicity that follows recall and testing of patients may lead to unwarranted fear and avoidance of endoscopy in the community, leading to missed opportunities for diagnosis and treatment;
- b) A small number of patients who are notified of a risk, even a very small risk, are reported to suffer “nervous shock;”
- c) Patient follow up is costly in terms of time and other resources.

The resulting patient benefit is likely to be small as transmission of significant infection is rare even when an error in reprocessing occurs<sup>297,298,299</sup>.

- a) It often is uncertain how long an identified problem has existed; patients who had their endoscopic procedure before the problem developed may be unnecessarily recalled and tested.
- b) Patients with previously undiagnosed blood-borne virus infection may falsely attribute this to the endoscopy.

Scenario	Immediate action	Investigations
Single patient with alleged disease following endoscopy	<p>Arrange clinical review of the patient to:</p> <ul style="list-style-type: none"> <li>• Ensure patient wellbeing</li> <li>• Determine microbial cause</li> <li>• Identify other possible causes of disease or sources of infection.</li> </ul> <p>External clinical input is necessary but should not deter ongoing clinical involvement by staff from the unit under investigation.</p>	<p>If plausible and temporal link to endoscopy then:</p> <ul style="list-style-type: none"> <li>• Look for other cases (this may involve contacting patients who had endoscopy at that time for clinical review and laboratory testing for the same disease or micro-organism).</li> <li>• Case-control analysis may be required to determine a link with endoscopy.</li> <li>• Review endoscopy unit documentation, protocols and relevant equipment and products.</li> <li>• Review surveillance cultures.</li> <li>• Analyse Quality Control (QC) and tracking records for any common link between affected cases (same endoscope, AFER, staff member etc.).</li> </ul>
Cluster of patients with similar diseases following endoscopy	<p>Arrange clinical review of patients to:</p> <ul style="list-style-type: none"> <li>• Ensure patient wellbeing</li> <li>• Determine microbial cause.</li> </ul> <p>External clinical input is necessary but should not deter ongoing clinical involvement by staff from the unit under investigation.</p> <p>Withdraw endoscope(s) or AFER(s) or rectify protocol if implicated by initial investigation of cases.</p> <p>If hepatitis C then consider multi-dose sedative vial contamination or inappropriate reuse of single-use items used for preparation and administration of procedural sedative.</p>	<ul style="list-style-type: none"> <li>• Look for other cases (this may involve contacting patients who had endoscopy at that time for clinical review and lab testing for the same disease or micro-organism).</li> <li>• Case-control analysis may be required to determine a link with endoscopy.</li> <li>• Review endoscopy unit documentation, protocols and relevant equipment and products.</li> <li>• Review surveillance cultures.</li> <li>• Analyse QC and tracking records for any common link between infected cases (same endoscope, AFER, staff member etc.).</li> </ul>
Cluster of positive cultures for same micro-organism following endoscopy	<p>Arrange clinical review of patients with positive cultures to ensure patient wellbeing.</p> <p>Withdraw endoscope(s) or AFER(s) or rectify protocol if implicated by initial investigation of cases.</p>	<ul style="list-style-type: none"> <li>• Look for other cases (this may involve contacting patients who had endoscopy at that time for clinical review and lab testing for the same micro-organism).</li> <li>• Review endoscopy unit documentation, protocols and relevant equipment and products.</li> <li>• Review surveillance cultures.</li> <li>• Analyse QC and tracking records for any common link between positive cultures (same endoscope, AFER, staff member etc.)</li> <li>• Carry out targeted environmental sampling.</li> </ul>
Defect in equipment or product or breakdown in protocol	<p>Stop using any defective equipment or products.</p> <p>Impound any items that may not have been properly reprocessed.</p> <p>Correct the defect or protocol.</p>	<ul style="list-style-type: none"> <li>• Determine the approximate duration of the problem.</li> <li>• Determine how serious the problem has been in terms of patient risk (review endoscopy unit documentation, compliance with protocols and surveillance cultures for the duration of the problem). Note that many processes have margins for error – a fault in your equipment or protocol may not indicate significant patient risk.</li> <li>• Determine the cause of the problem.</li> <li>• If significant problem, consider notification and review or testing of patients at risk.</li> </ul>
Positive surveillance cultures	See tables under Surveillance Cultures.	See tables under Surveillance cultures – pages 43-45.

### General principles of patient recall and testing

- a) Nominate a spokesperson for the group.
- b) Maintain a document register or 'trail'.
- c) Prepare written information regarding the problem, risks involved, rationale for action, how testing will be undertaken and how and when results will be made available.
- d) Contact affected patients early to inform them of the problem and the estimated risks. Successful notification or attempts at notification should be recorded.
- e) Apologise for the problem and emphasise the low risk of transmission of infection.
- f) If patient testing is indicated, the earlier this is done the better. Early identification of affected patients may expedite treatment, reduce the risk of further transmission and aid epidemiologic investigation. Early serological testing may help distinguish patients whose blood borne virus infection was pre-existing from those who acquired the infection through endoscopy.
- g) Patients at risk of blood-borne infections should be advised not to donate blood or tissue products or engage in sexual activity without barrier protection until serological testing is complete.
- h) Inform relevant staff within the organisation, General Practitioners in the area, health authorities and industry (e.g. AFER suppliers) representatives.
- i) If appropriate, make available a free video, telephone information line or one-to-one counselling service for patients and staff.
- j) The cost of patient recall and testing may be borne by the facility responsible for the problem, the local health authority or the manufacturer of faulty equipment.
- k) If the media are to be notified, ensure that patients are notified first. Prepare a media release in anticipation of media interest.

### What to test for

- a) Blood-borne viruses (BBV) (hepatitis B, hepatitis C, HIV) for patients who have had endoscopy around the time of suspected or proven endoscopy-related transmission of any micro-organism, a high-risk defect in equipment or breakdown in protocol, or a cluster of positive surveillance cultures that indicate a major defect in equipment or breakdown in protocol. Chase up records of previous blood-borne virus testing or vaccination. Perform baseline and follow-up testing according to local protocols for BBV exposure.

- b) Specific bacteria or mycobacteria in patients who underwent bronchoscopy at the time of an apparent outbreak (or pseudo-outbreak) of that micro-organism.
- c) *Mycobacterium tuberculosis* in patients who underwent bronchoscopy when there was a breakdown in protocol or high-risk defect found in the endoscope and at the same time a patient with known pulmonary or laryngeal tuberculosis underwent bronchoscopy using that instrument.

## Workplace health and safety in endoscopy

### Legislation

In each jurisdiction (Commonwealth, State or Territory) there is a principal Occupational Health and Safety Act that gives broad duties to the workplace parties. Commonly included in each Act are requirements for:

- Ensuring the workplace health and safety of employees at work;
- Providing systems of work that are safe and without risk to health;
- Preventing occupational injuries and diseases;
- Protecting the health and safety of others in relation to work activities, e.g. visitors.

The Act may also include requirements for:

- Providing a safe working environment;
- Providing information, instruction and training;
- Maintaining plant in a safe condition;
- Rehabilitation and maximum recovery from incapacity of injured employees.

The key principle in each Act is the 'duty of care'. This imposes obligations on employers to ensure the workplace health and safety of employees at work. This obligation extends to others such as contractors, patients and visitors. There is also an obligation on employees to ensure their own workplace health and safety and that of others, and to co-operate with employers on workplace health and safety matters.

Below are websites of the various State, Territory and Commonwealth government workplace health and safety sites.

Division of Workplace Health and Safety,  
Queensland  
**[www.whs.qld.gov.au](http://www.whs.qld.gov.au)**

WorkCover New South Wales  
**[www.workcover.nsw.gov.au](http://www.workcover.nsw.gov.au)**

Australian Capital Territory WorkCover  
**[www.ors.act.gov.au/workcover](http://www.ors.act.gov.au/workcover)**

Victorian Workcover Authority  
**[www.workcover.vic.gov.au](http://www.workcover.vic.gov.au)**

Workplace Standards Tasmania  
**[www.wsa.tas.gov.au](http://www.wsa.tas.gov.au)**

WorkCover Corporation, South Australia  
**[www.workcover.com](http://www.workcover.com)**

WorkSafe Western Australia  
**[www.safetyline.wa.gov.au](http://www.safetyline.wa.gov.au)**

Work Health Authority, Northern Territory  
**[www.nt.gov.au/wha](http://www.nt.gov.au/wha)**

Comcare Australia  
**[www.comcare.gov.au](http://www.comcare.gov.au)**

National Occupational Health and Safety  
Commission (NOHSC)  
**[www.nohsc.gov.au](http://www.nohsc.gov.au)**

Occupational Health and Safety Service,  
New Zealand  
**[www.osh.dol.govt.nz](http://www.osh.dol.govt.nz)**

As well as the sites listed above it is possible  
to link to copies of State/Territory legislation  
via the Australian Legal Information Institute at  
**[www.austlii.edu.au](http://www.austlii.edu.au)**

## Risk management

This is the process that underpins health and safety management. It involves systematically identifying hazards, assessing and controlling risks, and monitoring and reviewing activities to make sure that risks are effectively managed.

Effective consultation, training and information management are essential parts of the risk-management process and it can be applied to all workplaces.

## Biological hazards

One of the main hazards to those reprocessing endoscopes and accessories is that posed by the risk of acquiring an infectious disease from blood and other body fluid exposure. For a discussion of the infectious agents that can contaminate endoscopes see the section on Infecting micro-organisms – pages 10 to 16.

The risk relates to the handling of a used endoscope and the potential for splashing and the production of aerosols during manual cleaning. Aerosols create three risks during cleaning:

1. The risk of exposure to infectious micro-organisms contained in the aerosol.
2. The risk of exposure to chemicals contained in the aerosol.
3. The risk of environmental contamination due to aerosols from the cleaning process being dispersed and deposited throughout the area.

It is imperative that cleaning techniques should be designed to avoid splashing and the generation of aerosols and that the layout of the endoscopy unit should include clearly defined areas for contaminated, clean and sterile equipment to avoid cross-contamination.<sup>14</sup>

## Standard Precautions

When cleaning and handling used items, follow Standard Precautions at all stages of handling to prevent exposure to blood and body substances. Standard Precautions involve treating blood and body substances of all persons as potential sources of infection independent of diagnosis or perceived risk. Appropriate personal protective equipment (PPE), such as gloves, specifically designed fluid repellent masks/eye protection/face shields and fluid resistant aprons or gowns should be worn when handling used endoscopes and accessories.

The reprocessing area is potentially a contaminated area and as such non-essential personnel should be excluded and food should not be consumed in this area.

## Special Precautions for patients with antibiotic-resistant or other highly infectious micro-organisms

Standard Precautions are designed to protect staff against the vast majority of infectious micro-organisms carried by patients. Some patients, however, carry infections that are much more likely to be transmitted to endoscopy staff (e.g., norovirus, tuberculosis) or that could have medical consequences if acquired by or transmitted via endoscopy staff (e.g. multi-resistant bacteria, *Shigella* sp., influenza) or the clinic environment (e.g. *C. difficile*, VRE). Common multi-resistant bacteria in Australia and New Zealand include multi-resistant *Staphylococcus aureus*, extended-spectrum Beta-lactamase-producing gram-negative bacilli, multi-resistant *Acinetobacter* species, and vancomycin-resistant enterococci. Ideally, patients who are highly infectious should not have endoscopy until their infectivity is reduced but if endoscopy is deemed urgent then additional Transmission-Based Precautions are needed for staff who have direct contact with these patients. Note that there is no need for change to the protocols for cleaning or reprocessing of endoscopes used on patients with any infection other than suspected variant CJD (see page 15).

The protocols for Transmission-Based Precautions will vary a little depending on both the prevalence and virulence of micro-organisms within a given institution but the general principles in place do not significantly vary from healthcare centre to healthcare centre. Consult your local infection control team for advice. In general, the specific protocols for endoscopy staff handling patients carrying such micro-organisms include:

1. Contact-transmission micro-organisms (e.g. multi-antibiotic resistant bacteria, norovirus) - the wearing of personal protective equipment such as plastic aprons or gowns and gloves and the maintenance of scrupulous hand hygiene. Some units will also have protocols for cleaning the room after a patient with a high-risk micro-organism has undergone endoscopy.
2. Droplet-transmission micro-organisms (e.g. influenza) – the wearing of surgical masks when within 1 metre of the patient.
3. Airborne-transmission micro-organisms (e.g. measles, chickenpox, tuberculosis) – use a room with negative-pressure ventilation with at least 12 air changes per hour for the procedure and recovery. All staff in the room should wear a close-fitting P2 (N95) particulate respirator mask (only necessary if non-immune for a measles or chickenpox patient) during the procedure and

for approximately 20 minutes after the patient has left the room. Staff should receive instruction and training in the use of these respirator masks<sup>300</sup>. During recovery patients should also be provided with a P2 (N95) mask with no exhalation valve. Remember that patients with possible TB should not undergo bronchoscopy unless there are exceptional circumstances<sup>55</sup>.

## Management of sharps and sharps injuries, blood and body fluid exposure

All endoscopy units should have an appropriate sharps disposal policy. Sharps injury poses a very real threat of disease and careless practices by medical or nursing staff should not be tolerated.

All endoscopy units should have a clearly defined policy for sharps injuries and blood and body fluid exposures. In general this should follow the protocols laid out in state health department Infection Control Guidelines.

It is essential that prompt action be taken to report an occupational exposure so that immediate counselling, evaluation and treatment can be instigated. When it has been recommended, anti-retroviral therapy is most effective when commenced as soon as possible.

## Immunisation

Immunisation is a measure by which some protection from infection due to occupational exposure can be given to health care workers (HCWs). It is important that staff are aware of their immune status.

The National Health and Medical Research Council (NHMRC) in their most recent edition of 'The Australian Immunisation Handbook 9th ed. provides detailed information on immunisation schedules and vaccines<sup>301</sup>. Staff vaccination programs should comply with these procedures which acknowledge that there may be some circumstances that require special consideration before vaccination, for example, where a HCW is pregnant.

The NHMRC recommendations state that HCWs should be vaccinated against infections they may encounter. These may include hepatitis B, hepatitis A, measles, mumps, rubella, influenza and varicella.

Section 22 of The Communicable Diseases Network Australia (CDNA) publication 'Infection Control Guidelines' sets out more specific guidelines for immunisation of HCWs<sup>302</sup>.



From this document a recommendation of particular importance in endoscopy is:

1. Hepatitis B vaccine - particularly to those with potential exposure to blood or body substances (with post immunisation testing to identify non-responders) as soon as possible before or after starting work.

And some special circumstances these may also apply:

2. Mantoux tuberculin test negative HCWs at high risk may be offered BCG vaccination.
3. HCWs likely to encounter hepatitis A (e.g. in communities with substantial indigenous populations, custodial carers and carers of the intellectually impaired) should be immunised.

Each State or Territory may also have their own guidelines for immunisation of HCWs that should also be followed.

## Hazardous substances

Hazardous substances are chemicals and other substances that can cause injury, illness or disease. The health effects may be acute or chronic.

Workplace health and safety regulations exist in each State or Territory to protect against exposure to hazardous substances at the workplace. You should notify workplace health and safety personnel at your workplace if you suspect that exposure to a hazardous substance is causing health effects.

In this section the examples used will be for glutaraldehyde but the same principles apply for all hazardous substances. A great deal of information about glutaraldehyde is available at the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) website<sup>303</sup>.

The manufacturer or importer of a substance is responsible for determining whether or not it is hazardous. A substance is deemed hazardous if:

1. It is listed on the NOHSC 'List of Designated Hazardous Substances'.
2. It meets the criteria in the NOHSC 'Approved Criteria for Classifying Hazardous Substances'.

If a substance does not meet either of these criteria and you consider that it is causing adverse health effects in your workplace then the avenues for the investigation and reporting of this are:

1. Supervisor.
2. Workplace health and safety representative.
3. Workplace health and safety officer.
4. State/territory workplace health and safety department.
5. NOHSC.

Workplace health and safety regulations exist in each State or Territory for hazardous substances. These regulations place responsibilities on people including suppliers, manufacturers and employers for hazardous substances. Hazardous substances regulations differ between each State or Territory, and therefore the following discussion only provides an overview of the legislation. You should refer to the regulations in your particular State or Territory to find out what its specific requirements are.

Suppliers of hazardous substances must:

- Produce a current Material Safety Data Sheet (MSDS) for each hazardous substance they supply.
- Provide the MSDS to the purchaser at least the first time that the substance is supplied and when the MSDS is amended or revised.
- Label the substance in accordance with the regulations.

The employer is required to:

- Obtain a current MSDS for all hazardous substances used in the workplace.
- Keep a register that includes a list of all hazardous substances used in the workplace and the current MSDS for each one.
- Ensure that all containers of hazardous substances are appropriately labelled.
- If a hazardous substance is decanted from its original container into a second container this must also be appropriately labelled with the product name and relevant risk phrases and safety phrases as they appear on the original container's label e.g. 'R36 Irritating to eyes', 'R38 Irritating to skin'.
- Conduct and keep records of a risk assessment.
- Conduct and keep records of environmental monitoring and health surveillance if indicated by the risk assessment.
- Provide and keep records of induction and on-going training.

## Material Safety Data Sheet (MSDS)

An MSDS provides information about the hazardous substance that will assist with the risk assessment. It contains information about the substance such as:

- A statement indicating whether it has been classified as hazardous to health in accordance with NOHSC criteria
- The contents
- What it should be used for and how to use it safely
- Its health effects
- First aid instructions
- Advice about safe storage and handling
- Instruction on management of spills

The information you need about any hazardous substances used in your workplace is:

- The ways in which the substance enters the body, e.g. skin absorption, inhalation or ingestion
- What the acute and chronic health effects are
- The NOHSC exposure standard for the substance
- The recommended control measures

## Risk assessment of a hazardous substance

The risks involved in using the hazardous substance need to be assessed and managed following the process outlined in the risk management section.

In order to make an assessment of the risks involved in the use of a hazardous substance some more information is needed. As well as the information identified from the MSDS it is necessary to identify:

- Where and how the substance is used
- Who is likely to be at risk from exposure to the substance
- The tasks which may cause exposure
- Whether monitoring or health surveillance is required
- Whether anyone is showing health effects from exposure
- What controls are already in place, whether these controls are effective in managing the risk and if they should be reviewed

For more information on this process see <http://www.deir.qld.gov.au/workplace/subjects/hazardousmaterials/definition/risk/index.htm#conducting>

A risk assessment should be conducted and documented every 5 years or earlier if:

- A work practice involving a hazardous substance is significantly changed
- New information about the substance is available
- Health surveillance or monitoring shows control measures need to be reviewed
- New or improved control measures are implemented

If you need to perform a risk assessment of any hazardous substances used in your workplace it would be advisable to contact your WH&S personnel who will provide you with assistance. Examples of the risk assessment process as applied to the use of glutaraldehyde, peracetic acid or orthophthalaldehyde are provided at [www.health.qld.gov.au/endoscopereprocessing/default.asp](http://www.health.qld.gov.au/endoscopereprocessing/default.asp)

## Reproductive hazards

Reproductive hazards can arise from hazards such as biological hazards and hazardous substances. Hazardous substances that are teratogenic are able to produce abnormalities in a developing foetus.

If you have any concerns regarding reproductive risks you should discuss this with WH&S personnel or your medical practitioner for advice on fitness to work with any hazardous substances whilst pregnant.

## Personal protective equipment

The possibility of splashing by blood, bodily fluids and hazardous substances is not necessarily predictable and all those likely to encounter splashing should wear PPE.

It is also important to use work practices that can minimise the likelihood of splashing and the production of aerosols.

## Clothing

Fluid repellent gowns that provide full skin protection for arms and legs should be worn when reprocessing flexible endoscopes and accessories. They should be changed if soiled.

The relevant Australian Standards are:

- AS 3789.2 Textiles for health care facilities and institutions – Theatre linen and prepacks
- AS 3789.3 Textiles for health care facilities and institutions – Apparel for operating theatre staff

## Eye protection

For handling hazardous substances, where splashing of the concentrated solution may occur, chemical safety goggles should be used.

For handling small quantities of dilute solutions, chemical safety spectacles with side shields may suffice.

When reprocessing endoscopes, face shields should be used to protect from exposure to biological and chemical hazards.

The selection and use of eye protection should be in accordance with the Australian Standards:

- AS 1336 Recommended practices for occupational eye protection
- AS 1337 Eye protectors for industrial applications

## Respiratory protective equipment

To prevent exposure to aerosols or splattering a fluid-repellent, deflector mask or face shield should be worn when reprocessing flexible endoscopes and accessories.

If there is a risk of airborne infection, as in bronchoscopy, a close-fitting, disposable, particulate filter respirator should be worn. In the absence of an Australian Standard it is recommended in 'Infection Control Guidelines' Section 13.4 that respirators that meet the United States N95 standard be used<sup>302</sup>. The Australian equivalent is a P2 respirator.

In case of spills of hazardous substances when respiratory protection is required, a half-face respirator with organic vapour cartridge should be available. Cartridges should be replaced at regular intervals in accordance with the manufacturer's recommendations.

The relevant Australian Standards are:

- AS/NZS 1715: Selection use and maintenance of respiratory protective devices
- AS/NZS 1716: Respiratory protective devices

## Gloves

Gloves used when reprocessing endoscopes must be impervious to the cleaning agents and disinfectants being used. If single-use gloves are not used then the reusable gloves should be washed in soapy water, rinsed and dried after each session; otherwise they may become permeable. They should be stored dry after use and replaced if torn, cracked, peeling or showing signs of deterioration.

The permeability of different gloves to increasing concentrations of glutaraldehyde has been assessed by permeation tests. PVC and neoprene gloves have been found to retain or absorb glutaraldehyde on

extended exposure. Nitrile rubber or butyl rubber gloves provide the best protection. Latex gloves provide protection for approximately 45 minutes. However, the issue of latex allergy may impact on the choice of gloves.

Latex allergy is an increasing occupational health and safety problem and can vary from mild to very severe. For more information about latex allergy go to the CDC website <http://www.cdc.gov/niosh/topics/latex/>

Because aerosolisation of latex particles is a major route of sensitisation, the use of powder-free gloves is advisable.

For latex-sensitive individuals, gloves made from alternative products such as nitrile, butyl rubber, vinyl and neoprene are available. However, consideration needs to be given to the suitability of the material for use with the disinfectants and cleaning agents used for reprocessing.

The Australian Standards for gloves are:

- AS/NZS 4179: Single-use sterile surgical rubber gloves – Specification
- AS/NZS 4011: Single-use examination gloves – Specification
- AS/NZS 2161.2: Occupational protective gloves – General requirements

## Guideline application statement

These guidelines have been prepared by the Gastroenterological Nurses College of Australia and the Gastroenterological Society of Australia and every care has been taken in their compilation. The guidelines are intended to be used as a guide only and not as an authoritative statement of every conceivable step or circumstance that may or could relate to the performance of the procedures outlined. Practitioners should use these guidelines as an aid in relation to disinfection and not as a complete or authoritative statement of such procedures.

The Gastroenterological Society of Australia, the Gastroenterological Nurses College of Australia and the compilers of these guidelines shall not be liable to users of these guidelines nor to any other person, firm, company or other body for any loss, direct, indirect or consequential, on whatsoever account for any omission or negligent mis-statement contained herein, or by reason of, arising from or in relation to any such user, by any other person, company or body relying or acting upon or purporting to rely or act upon any matter contained therein or arising thereout.

## Appendix A: ‘proof of process’ for flexible endoscopes

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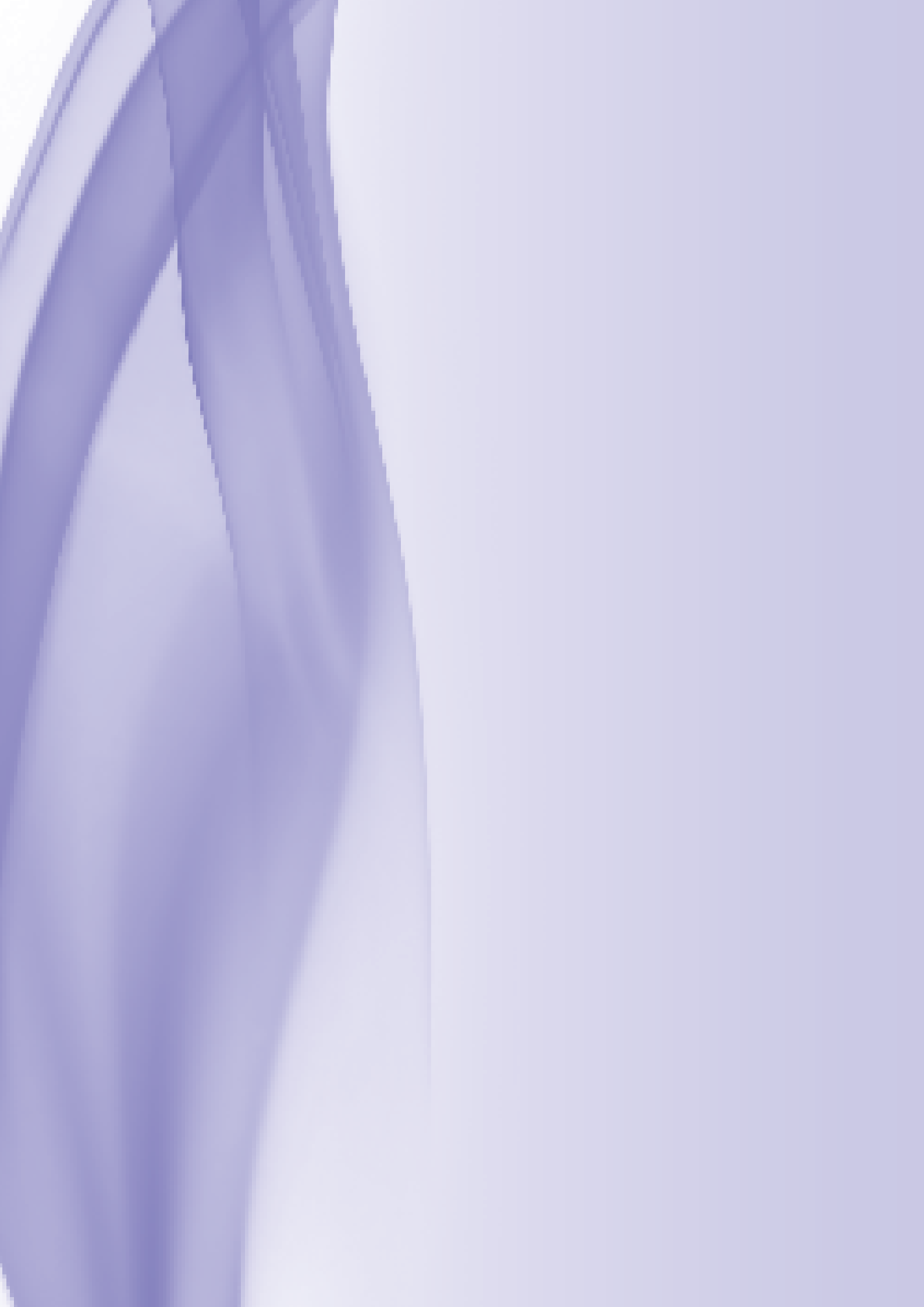
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